Summary Report of the EPA/ACC Technical Workshop for the Voluntary Children's Chemical Evaluation Program (VCCEP)

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NOTICE

The statements in this report reflect the views and opinions of the workshop participants. This report was prepared by ERG, Inc., an EPA contractor, as a general record of discussion held during the EPA/ACC Technical Workshop for the Voluntary Children's Chemical Evaluation Program (December 11 – 13, 2001). This report captures the main points and highlights of the meeting. It is not a complete record of all details discussed, nor does it restate, interpret, or enlarge upon matters that were incomplete or unclear.

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EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency and the American Chemical Council jointly sponsored a three-day workshop on December 11-13, 2001 to provide a forum for sharing ideas about resources and approaches for collecting and presenting exposure information under the Voluntary Children's Chemical Evaluation Program (VCCEP). Members of industry, EPA employees, and persons representing public interest groups made presentations on assessing children's exposure to chemicals. An invited panel of experts was asked to comment upon the presentations. Subsequently, members of the audience were provided the opportunity to comment and to ask questions of the presenters and panelists.

Approximately 120 stakeholders representing industry and regulatory agencies attended the workshop. Twenty participants were invited to make presentations, and 18 panelists were invited to participate in roundtable discussions on these presentations. The workshop consisted of four parts:

Part I: Background: The opening session consisted of presentations explaining the purpose of VCCEP and the workshop, the role of industry in VCCEP, and the importance of sound science in VCCEP.

Part II: Exposure: The second part of the workshop focused on exposure assessments subdivided into four sections. Section A presentations provided an overview of exposure assessments, and Section B presentations provided information on resources and models that may be used to compile an exposure assessment. An example exposure assessment was presented in Section C along with a framework for integrating exposure information. Section D contained presentations on EPA's draft Summary for Presenting and Characterizing Exposure Information and an example illustrating how to complete EPA's draft Summary.

Part III: Peer Consultation, Hazard and Risk Assessment, and Data Needs: The third part of the workshop contained information on the VCCEP peer consultation process, an overview of EPA's perspectives on hazard and risk assessment, and data needs for the VCCEP.

Part IV: Closing Remarks: Closing remarks were made by Dr. Michael Kaplan representing the American Chemistry Council, Dr. George Lucier, Adjunct Senior Scientist for Environmental Defense, and Dr. Mary Ellen Weber, Director of the Economics, Exposure and Technology Division (EETD) in the Office of Pollution Prevention and Toxics, US EPA.

Each part of the workshop consisted of a series of presentations by EPA, industry, and other stakeholders. The presentations were followed by questions and discussion, first from the invited panelists, and then from the audience.

Appendix 1 to this report contains the agenda for this meeting. Appendix 2 contains the invited panelist biographies and Appendix 3 contains the presenter biographies. Slides from each presentation at the workshop are available on the EPA Chemical Right-To-Know website at http://www.epa.gov/chemrtk/expagnda.htm by clicking on the title of each presentation in the agenda.

1.0 PART I: BACKGROUND

Part I of the workshop included presentations on the following topics:

Welcome and Introduction: Steve Johnson, Assistant Administrator, Office Prevention, Pesticides, and Toxic Substances, EPA

Purpose of Workshop: Mary Ellen Weber, Ph.D., Director, Economics, Exposure, and Technology Division, EPA

Orientation to VCCEP: Ward Penberthy, Associate Director, Chemical Control Division, EPA

Industry Participation in VCCEP: Bill Greggs, Regulatory Affairs Manager, The Procter and Gamble Company

Importance of Sound Science in VCCEP: George Lucier, Ph.D. Consultant to Environmental Defense

Detailed descriptions of the topics covered and discussions resulting from each presentation are provided in the remainder of this section.

1.1 Welcome and Introduction

Steve Johnson, Assistant Administrator, EPA/OPPT

Mr. Johnson described the three themes under which EPA operates: 1) Partnerships - problems are more easily and more effectively addressed through partnerships; 2) Innovation - ideas and innovations come from partnerships with people and organizations both within and outside of Washington, DC; 3) Results - partnerships and innovations are for naught without results. The VCCEP and HPV programs are examples of the implementation of these themes. Mr. Johnson noted the Agency's interest in pursuing these programs, and stated that the Office of Prevention, Pesticides, and Toxic Substances consider the VCCEP and HPV programs top priorities.

Mr. Johnson closed his comments by stating that the VCCEP and HPV programs will face challenges. The programs will need to stay focused. Also, some chemicals lack available hazard and exposure data. These deficiencies will need to be recognized and characterized as part of the Tier 1 assessment. Finally, the peer consultation is an untested idea that has the potential to play an important role in future activities.

1.2 Purpose of Workshop

Mary Ellen Weber, Ph.D. Director, EPA/EETD

Dr. Weber presented the primary purpose of this workshop: to support the VCCEP sponsors. EPA had promised to provide a forum for presenting various approaches to collect and present exposure information. The VCCEP workshop was that forum for members of industry, EPA, and persons recommended by public interest groups to present their approach.

Dr. Weber named a second goal of the workshop: to provide the participants with an opportunity to share ideas about resources, methodologies, and approaches. EPA hopes for movement toward a consistent framework of reporting exposure assessment information so that information is easily accessible, consistently available, and transparent while acknowledging the uniqueness of the chemicals and their circumstances.

The workshop panel included 15 people. Five were identified by industry, five were identified by public interest groups, and five are from various areas of government. Dr. Weber acknowledged that the panel was present to discuss the presentations, but audience participation was also solicited and important.

Dr. Weber concluded her remarks noting that VCCEP is a voluntary, pilot program, and 20 of the 23 pilot chemicals have sponsors. The program requires flexibility, in that not all scenarios and data elements will be required for each chemical; however, the absence of data should be explained so that the reader does not misinterpret the absence as an oversight or an accident. Although there will be a brief discussion of risk assessment data needs and a TERA presentation of the peer consultation process at this workshop, it is not a goal of this workshop to identify a generic method of characterizing risk. EPA does hope that this workshop will assist the stakeholders and the partners in gathering and describing exposure information. The workshop will describe resources, databases, methodologies, and established guidance documents as well as present alternative formats that support the principles of transparency, consistency, quality, and completeness.

1.3 Orientation to VCCEP

Ward Penberthy, Associate Director, EPA/CCD

Mr. Penberthy began his remarks by stating that VCCEP was designed via a stakeholder process begun about 18-20 months ago during 3 public meetings. Through that process, VCCEP became more than a testing program, but also an exposure and risk assessment program. A Federal Register notice was issued on December 26, 2000 announcing the program. This notice should be an initial resource for any questions about the program.

VCCEP is a pilot program that will determine how to create the final design of this process. A key portion of this pilot is to test the viability of the peer consultation process and the

tiered-testing scheme. EPA is committed to evaluating the program at 3 years and at 6 years (from the date of the FR notice).

Mr. Penberthy stated the goal of the program is to make risk data available to the public. The chemicals included in the program were chosen based on biomonitoring data. The program includes a tiered scheme, in which sponsors make commitments tier-by-tier. For each tier, sponsors prepare a data package including a hazard, exposure, and risk assessment, as well as an assessment of information needs for the next tier. Sponsors submit their assessments to the peer consultation panel.

Mr. Penberthy further explained that the peer consultation is a forum of scientists and experts for exchanging views on the sponsors' assessments. It is not designed to be a consensus, but rather, it is a mechanism to identify all pertinent issues. Results and comments from the peer consultation will be compiled by an independent third party (TERA). TERA will create a report that will be made publicly available. The peer consultation will evaluate the submissions based on the standard, "Are the data sufficient to adequately characterize the risks of the chemical to children?"

Mr. Penberthy noted two key elements of exposure assessments: transparency and completeness. Sponsors are encouraged to make conservative, quantitative estimates of exposures to children using established guidelines such as those found in the Child-Specific Exposure Factors Handbook. Assessments should include all manufacturing processes that could lead to exposure to children or prospective parents. All industrial, commercial, and consumer uses leading to exposure to children should also be covered. Estimates of environmental releases, physical/chemical properties, environmental fate, activity patterns, age ranges, and sub-populations exposed should be included. Every assessment will also include estimates of extent, duration, and frequency of exposure. The presentations in this workshop will address these principles and present possible approaches to conducting exposure assessment.

1.4 Industry Participation in VCCEP

Bill Greggs, Regulatory Affairs Manager, Procter & Gamble

Mr. Greggs explained industry's perspective on their participation in VCCEP. The VCCEP pilot is testing whether a voluntary program can establish an effective process for making science-based judgements about risk to children. Mr. Greggs stated that it is important that the program not try to answer every question about every chemical. Reviewers of the assessments should receive consistent, transparent, and scientifically sound information with regard to exposure, with the flexibility to recognize the variety of approaches that will exist from chemical to chemical.

Industry's objective for the program is to focus on exposures to children and provide a better alternative to a regulatory approach. Industry supports the tiered approach of the pilot program. Industry also supports an integrated hazard and exposure assessment that enables a risk-based evaluation. The assessments should be consistent and yet flexible. Industry advocates the integration of this effort with others to achieve efficiencies that will conserve financial, animal, and human resources. Industry is committed to this program as evidenced by the fact that 87% of the pilot chemicals have sponsors thus far. One of the keys to industry's commitment is EPA's commitment to considering flexible and data-driven approaches to reducing risk to children.

Mr. Greggs closed his remarks formally accepting Mr. Johnson's invitation to proceed as partners in this effort.

1.5 Importance of Sound Science in VCCEP

George Lucier, Ph.D., Consultant to Environmental Defense

Note: The agenda shows that George Lucier's presentation as the last presentation in Part 1: Background. Due to unforeseen circumstances, Dr. Lucier gave his presentation during Part II of the workshop rather than as scheduled in Part I. The summary of his presentation is provided in Section 1.5 of this document to maintain the consistency of the topics.

Dr. Lucier opened his presentation by welcoming the panel and audience, and applauding their efforts in developing VCCEP. This is a voluntary pilot program, and demonstrates the good will and good intent of the American Chemistry Council. This program is very similar to the Alliance for Chemical Awareness program addressing high production volume chemicals. There are many lessons that may be learned from these simultaneous activities that may be applied to VCCEP.

Dr. Lucier stated that exposure assessment has been neglected in the past. VCCEP emphasizes the importance of exposure assessment within the context of defining exposure-response relationships. Exposure assessments are an essential part of disease prevention. This

program is attempting to define exposure circumstances under which children may be exposed so that resulting health effects can be prevented.

Dr. Lucier noted that exposure assessment should be discussed in the context of the related issues of risk and hazard, and consider the following points:

1) There is a great information weakness in the endpoint-specific effects of chemicals as well as weaknesses in some available exposure data. It will be difficult to complete an initial analysis of exposure that adequately communicates the uncertainty which surrounds that assessment.

2) How do we address cumulative and aggregate exposures?

3) How do we best take advantage of information developed through other exposure assessment programs, such as the NHEXAS through EPA and NHANES through CDC, and how do we take advantage of these data and influence those programs in order that we may extract information that is needed for the VCCEP program?

4) What endpoints are important in assessing the impacts of children's exposure?

5) How do we deal with metabolism and breakdown products? A non-detect measurement does not necessarily indicate that a person was not exposed.

6) How can we keep from over-simplifying?

7) Children are likely to be more sensitive than adults to the toxic effects of chemicals.

8) Exposure information exists for some chemicals and is sometimes good and sometimes weak.

There are a lot of questions to keep in mind and on the table. It is important to identify the questions for which we have answers and those that we need to investigate. The openness, transparency, review, and availability of information will be critical in this program.

2.0 PART II: EXPOSURE SUMMARIES

Part II of the workshop focused on exposure, and was divided into four sections:

A. Overview of Exposure Assessment;
B. Resources and Models;
C. Example Exposure Assessments; and
D. EPA's Draft Exposure Summaries.

2.1 Overview of Exposure Assessments

Part II A of the workshop began with an overview of exposure assessment presented by Cathy Fehrenbacher, Chief of EPA's Exposure Assessment Branch. Richard Becker, Senior Director of the American Chemistry Council (ACC), presented Perspectives on Tiered Exposure Assessments for VCCEP. Rosemary Zaleski of ExxonMobil Biomedical Sciences presented an approach for assessing children's exposures. Finally, Dr. Elaine Cohen Hubal presented an overview of Children's Exposure Assessment.

2.1.1 Overview of Exposure Assessment

Cathy Fehrenbacher, Chief, EPA/EETD/Exposure Assessment Branch

Ms. Fehrenbacher briefly described three approaches EPA uses to conduct exposure assessment. Exposure can be measured at the point of contact (e.g. monitoring), exposure can be estimated using a scenario evaluation, and exposure can also be reconstructed using biomarkers to estimate internal dose.

Ms. Fehrenbacher defined some common terms used in exposure assessment. An exposure pathway defines the path that a contaminant takes from the source of the contaminant to the receptor's portal of entry. For any exposure pathway, there are associated exposure scenarios, which includes the source of a contaminant, the population with potential for exposure, the time frame in which the exposure occurs, the microenvironment, the macroactivity, and the microactivity. The microenvironment is a specific description of the place that an individual occupies during the activity. A macroactivity is a general description of what an individual is doing while there is potential exposure, and the microactivity is the specific physical acts that are occurring during the exposure.

The goal of an exposure assessment in terms of a risk assessment is often to estimate a dose. That dose is combined with chemical-specific dose-response data to estimate risk. For a screening-level assessment, semi-quantitative approaches may be appropriate, where data is unavailable or needs to be supplemented. Screening level exposure assessments are often iteratively revised to include more quantitative information at higher tiers.

Ms. Fehrenbacher explained that VCCEP sponsors have committed to preparing a Tier 1 assessment, which includes a hazard assessment, an exposure assessment, a risk assessment, and an assessment of further data needs. The Tier 1 exposure assessment is a screening-level assessment of readily available data to cover all aspects of the chemical's life cycle. The reader should be able to make an independent conclusion based on the data presented (transparency), and the reader should be able to readily identify what exposures are included in the assessment, what exposures are not included, and why they were not included (completeness). The exposure estimates should be characterized by providing the potential routes of exposure, amounts (concentrations, dose rates, aggregate exposures), duration and frequency of exposure, and the populations of relevance. The quality of the data and estimates should be characterized.

Ms. Fehrenbacher explained this approach using a generic manufacturing scenario and an example exposure scenario for a paint product. The pathway, scenario for children, and scenario approach were outlined using the principles and definitions described previously.

A number of sources were suggested for obtaining information and data useful for developing an exposure assessment. The locations of several resources available over the Internet were provided. A list of these resources can be found on the hard copies of slides from this presentation.

Clarifying Questions:

Panelist Question: I am interested in your overview of how differently aged children will be handled in an exposure assessment.

Presenter Response: There will be two additional presentations that will specifically address this issue. The presentations by Elaine Cohen Hubal and Jacqueline Moya will address this issue, and I would prefer to defer this question to those presentations.

Panelist Question: This was a topic of a whole conference in which the conclusion was that age bins are a very serious problem. They are not simple to use and not physiologically appropriate. The discussion at that conference concluded that there needs to be an alternative way to deal with this.

Audience Question: Could you please define what the screening-level assessment is not?

Presenter Response: It is not the collection of additional monitoring data. It is not a very definitive advanced exposure assessment. The screening-level assessment is where you bring forth readily available data and information and put it into a risk assessment context. The

advanced exposure assessment would use monitoring studies that are well designed, conducted, and representative. For the screening-level assessment, if you have advanced data, you can bring it forward; however, you are not required to develop an advanced exposure assessment or collect additional monitoring data. The screening-level exposure assessment does not include collection of additional monitoring data and it does not necessarily include the use of advanced modeling and monitoring data unless it is available. The screening-level exposure assessment will need to be tailored to the particular chemical.

Audience Question: What do you consider to be readily available? Some of these chemicals are very data rich, and we are considering both children and prospective parents. How far are we expected to go with this? There are a lot of data that have been collected over the years.

Presenter Response: The level of data needed should be evaluated on a chemical by chemical basis. EPA's expectation is that the sponsor will do their best to look at the references and resources that will be presented here, and to bring forth all of the information that you know about. Use your company database, national databases, and literature searches. All of the references and resources that are discussed in this workshop are considered readily available.

Panelist Question: Would it be reasonable to suggest that the sponsor should not necessarily use all readily available information, but only relevant information needed to support a credible science-based assessment?

Presenter Response: Yes, the characterization of completeness in the assessment summary should describe information that was available, but not included as part of the assessment, and why it was not included in the assessment.

Panelist Question: Would a screening-level assessment include both deterministic and probabilistic assessments?

Presenter Response: Yes, both could be included. This is a decision that the sponsor would need to make.

Panelist Comment: A screening-level assessment does not need to include advanced, scenario-specific exposure factors. The sponsor should have the flexibility to define that data as part of the Tier 1 assessment.

Presenter Response: Yes.

Panelist Comment: Readily available information should only include data relevant to children and prospective parents as it pertains to VCCEP. Screening-level assessments will see a

fair amount of qualitative data that can be used to make good judgements about priorities and relative levels of exposure that will allow the sponsor to focus on scenarios with the highest exposure potentials.

Presenter Comment: The Agency uses a good deal of qualitative information for screening-level purposes where it is appropriate and where data is not available or needs to be supplemented. The sponsor should keep in mind that the purpose of these assessments is to develop an overall risk assessment that will at some point require quantitative exposure information.

Panelist Question: Regarding the concepts of totality, completeness, and relevance to children. Could you please provide clarification on this issue of wanting a complete assessment that is relevant to children and prospective parents?

Presenter Response: Again, whether prospective parents should be considered is a determination that the sponsor will need to make. In the end, the question is "Have the risks to children have been adequately characterized?" If exposures to prospective parents are relevant to answering that question, then that information should be included.

Panelist Question: What are your thoughts on the term "adequately characterized" in terms of exposure assessment.

Presenter Response: You will know it when you see it. The peer consultation group will be the first group to evaluate whether the potential risks to children have been adequately characterized. The Agency has provided our perspectives on what we mean by "adequately characterizing" exposures, and there are other standards of practice in exposure assessment which describe this. The EPA's Guidelines for Exposure Assessment and Risk Characterization Handbook provides guidance on this issue as well.

Panelist Question: I would like to reemphasize the importance of determining exposure to adults (as prospective parents) since the fetus may be the most susceptible to exposure. Sperm alterations in adult males may result from exposure to some chemicals.

2.1.2 Perspectives on Tiered Exposure Assessments for VCCEP

Richard A. Becker, Ph.D., Senior Director, American Chemistry Council (ACC)

Dr. Becker opened his remarks noting that assessing exposures to children is not a new concept. There is not a generic method for determining children's exposure to all chemicals in all circumstances, and there is no guidance available that will give step-by-step instructions on how to do an exposure assessment. There is, however, a goal to provide a scientifically sound assessment that adequately characterizes risk for a given chemical within a given tier. The peer consultation process provides a means for scientists and experts to discuss whether an assessment meets that goal.

Dr. Becker noted the critical components of an exposure assessment: scientific quality, completeness, and transparency. The exposure assessment places the hazard assessment in context to develop a risk assessment, focusing on children's exposures for VCCEP. Screening-level assessments employ readily available information to make conservative (worst case) estimates designed to identify and prioritize exposures for advanced assessments. Advanced assessments focus on the higher priority exposures and employ more sophisticated models or monitoring data in an attempt to represent actual environmental conditions.

Dr. Becker explained that VCCEP contains three tiers. Tier 1 assessments focus on the greatest potential exposures and include qualitative and semi-quantitative estimates of exposure based on conservative assumptions. Tier 2 assessments are more refined than Tier 1 assessments, and focus on the critical sources and pathways of exposures. Tier 3 assessments are the most detailed estimates of exposure, and include in-depth studies of the critical sources and pathways of exposure using specific monitoring and modeling data.

Dr. Becker concludes by asserting that there is no replacement for experience and knowledge in making exposure assessments. It is impossible to describe a check list approach to exposure assessments that will meet the needs of what is required to conduct exposure assessments for VCCEP.

2.1.3 General Discussion I

A panelist noted the omission of potential exposure to aggregate chemicals that may have similar toxicological properties. Dr. Becker responded by stating that VCCEP is a chemical-specific evaluation program. Another panelist expressed his concern about Dr. Becker's answer and suggested that although aggregate chemical exposure assessments are not part of VCCEP, typical exposures are not significantly additive. If additivity becomes a concern in the future, existing techniques for assessing mixture could be used. Another panelist raised the issue of practicality in assessing and screening a large number of chemicals. Such a cumulative assessment might be an option for a higher tier assessment as the program might be modified in the future.

A panelist requested elaboration on how the determination of significant and insignificant exposure pathways should be made. Dr. Becker stated that this determination could be done quantitatively or qualitatively. Quantitative models and methods that generate exposure estimates for all pathways from a given source are based on the physicochemical properties of the chemical in question and how it partitions into different media. Estimates generated using these methods and models for these same pathways are 1-3 orders of magnitude less than that of the dominant pathway. A semi-quantitative or "standard of practice" approach is based on experience, knowledge, and the properties of the chemical in question.

The same panelist followed up by offering the hypothetical case of a pathway that may not present a significant exposure relative to another pathway, but when taken in context with the hazard information for the chemical in question could present a risk of concern. Dr. Becker referred to a Sciences International presentation that suggests that hazard information be considered early on in the process so that the exposures of concern are not overlooked.

Another panelist commented that the risk characterization part of this program might be more challenging than preparing the exposure assessments. The panelist noted that the *de minimis* concept used in years past may have hindered risk characterization efforts by including sources that were insignificant when compared to the major drivers of exposure and risk. Dr. Becker responded by agreeing that, particularly for screening-level assessments, we should focus on the major contributors to exposure and potential risk.

A panelist asked about the impact of the selection process for the list of chemicals on the likelihood of assessments for those chemicals progressing into Tier 2. If Tier 2 assessments might take extended periods of time, it might be worthwhile to anticipate those Tier 2 issues and data needs. Also, since risk is population-based, one might see high risk to a small population or low risk to a large population, and not overlook the low risk scenarios. Dr. Becker agreed and reiterated that these assessments can not be approached from an inflexible, "one size fits all" process. Each assessment will involve different chemicals, scenarios, and behaviors. The

Sciences International report demonstrates how to focus on children. Exposure assessments will be addressed with a knowledge-based approach.

A panelist expressed concern with the "you'll know it when you see it" approach to determine the completeness of assessments. The panelist suggested providing specific guidance where possible. Dr. Becker responded that sponsors should use both the expectations of assessments under each of the three tiers when preparing assessments and a science-based process to determine how to focus on sources and pathways of exposures to children. Ultimately, the peer consultation process will judge the quality of that work.

A panelist commented that in preparing exposure assessments, there are issues of variability and uncertainty that can confound the process. It is important to consider what is meant by "screening-level assessments" and how they compare to Tier 2, 3, 4 assessments. Dr. Becker agreed with the comment.

A panelist noted that it has been assumed by the presentations thus far that chemicals are being used as prescribed by the manufacturer. This is hardly the truth in the real world. Children are exposed to chemicals that they should not be and non-recommended usage is often the cause. Dr. Becker responded that scientists should anticipate misapplications and misuse and address them if necessary. If an assessor overlooked such a scenario, it would most likely be brought to light during the peer consultation process. Another panelist added that consumer product manufacturers are required by law to examine both expected uses and known misuses in their exposure assessments.

An audience member asked for more information from the last panelist on whether the law requires exposure assessments resulting from intentional misuse of chemicals (i.e. suicide) or if the requirement is only for involuntary, accidental exposures from misuse. The panelist responded that only assessments of expected misuses (non-suicidal) are required. Another audience member clarified that the language used by CPSC is "reasonably anticipated misuse." Manufacturers of consumer products must anticipate both purposeful and accidental misuses of product and allow for risk assessment of the extent of those misuses

A panelist offered the anecdotal example of a detergent being used to clean oil from ducks in Alaska, without the knowledge of the manufacturer. Once this chemical use was discovered, the manufacturer added it to their risk characterization.

An audience member expressed concern for alarmist conclusions based on screening-level assessments of exposures to children and prospective parents, especially in regard to chemicals for which not much data are available. How much screening is screening and how much detail can be included to minimize alarmist concerns? Dr. Becker offered two answers. First, gain a better understanding of screening-level risk assessment. Artificially high estimates

in screening-level assessments provide a bias that may identify risks to certain chemicals for which there is actually no concern. On the other hand, it can be assumed that assessments made with such a bias that show no concern are in fact of no concern. These interpretations of what screening-level assessments are and are not must be effectively communicated. The second answer is to use better stochastic models to identify particular pathways of concern.

A panelist pointed out that this is a pilot program and will eventually be evaluated. Has the evaluation process been thought out? How will the success of the program be determined? Dr. Becker responded that although some work has been done on the evaluation process, the exact process has not been determined. He suggested that perhaps the panel or other panels could develop questions that need to be asked to gauge which components of the program are working well and which need to be improved. Determining the value added by this program, in terms of the understanding and awareness of chemical risks to children in light of the efforts and resources applied, will be the difficult question to ask.

An audience member indicated that many chemical companies are being bought or are merging with other companies. It is possible that a company may find itself as the sponsor for a chemical with which it has no experience. Do you have any advice for determining if a comprehensive search has been performed? Dr. Becker offered his (and ACC's) services as a resource for any sponsor seeking chemical-specific information or information on the VCCEP program. Also, becoming educated about the VCCEP process as well as utilizing EPA and the resources already listed in today's presentation should help address this concern.

A panelist revisited the question about alarmist reactions to screening-level assessments. Based on the experience of the panelist in performing screening-level assessments, what is NOT known about potential exposures can be very important. As long as the screening-level assessments are framed in the sense that they are a search for the unknown as well as a way to support what is known about exposure, they will reduce the level of fear and panic about potential pathways that prove to be inconsequential.

A panelist expressed concern that the process used to stop an evaluation at Tier 1 might be based on information that could be considered "weak" as part of a screening-level assessment. The panelist requested additional information about the process that will be used to determine whether or not the evaluation should be stopped at Tier 1. Dr. Becker suggested that the organization of the program answers this question. The four parts of the document (hazard assessment, exposure assessment, risk characterization, and data needs) that are submitted to the peer consultation panel, especially the data needs component, should answer that question for each chemical. This question cannot be answered in the abstract for all chemicals, but will be of particular concern as part of this pilot program.

A panelist followed up an earlier question related to the *de minimis* concept. When such an exposure threshold is established, it may also be necessary to address the need for aggregate exposure assessments. Simultaneous assessment of exposures for which there is little concern could combine to produce an aggregate assessment for which there is concern. In addition to identifying areas of further research and data gathering, screening-level assessments might also be used to determine which chemicals and pathways are good candidates for aggregate exposure assessments.

A panelist offered an opinion about the economics of screening assessments. Industry views screening-level assessments as a prioritization tool, but it is not an inexpensive process. Qualitative assessments and common sense are used initially to determine whether or not a substance poses a potential risk. Resources can then be focused on evaluating the substances and pathways of highest concern.

An audience member asked if the VCCEP process would encourage people to look at new ways of assessing children's exposures? Dr. Becker responded that this is a science-based process that involves gathering information and analyzing that information so that it can be built upon in other efforts. Part of the program review could include areas where EPA or other organizations should engage in other areas of research.

2.1.4 A Tiered Approach for Assessing Children's Exposures

Rosemary Zaleski, Senior Environmental Scientist, ExxonMobil Biomedical Sciences, Inc.

Ms. Zaleski presented a tiered approach for conducting children's exposure assessment. The approach is supported by the American Chemistry Council and published in Environmental Health Perspectives. The goal of the approach is to identify the substances and scenarios that present the highest potential risks to children. The approach is risk-based, and intended to align with the overall risk characterization goals of VCCEP.

Ms. Zaleski reviewed the unique aspects of children's exposure and noted that there is a lack of guidance specifically for conducting children's exposure assessments. Data are required that are specific to children, including physiological factors; air, water, and food intake rates; behavioral data; and activity data. Possible sources for these data are EPA's exposure factors handbooks, EPA workshops and activities, chemical manufacturers, literature, chemical databases, and trade organizations.

Ms. Zaleski presented a tiered approach to conducting children's exposure assessment, which consists of three primary steps. The first step is chemical selection. The chemical selection approach is based on the hazard and exposure components with respect to children, and is different than the VCCEP chemical selection process. The second step is to evaluate the initial

margin of exposure (MOE). The initial MOE is a conservative, but plausible estimate of exposure. The refined MOE uses more realistic model or monitoring data. If the MOE is high, then no further action is required. If the MOE is low, then the value should be used to prioritize the chemical for further evaluation.

Ms. Zaleski closed her presentation reiterating that the sophistication of the exposure assessment should be consistent with the overall risk characterization goals and the hazard data. The focus of the assessment should be on the areas of highest uncertainty. The process should be flexible, transparent, and logical.

2.1.5 General Discussion II

A panelist inquired about the need for and use of conservative assumptions in the approach. Ms. Zaleski responded that the key is to make sure that the basis of the information used is outlined in the assessment, as well as why certain data are used or not used. In the case of a distribution of data, an upper bound might be used. The panelist responded that it is important for the assessor to state not only that the data used are conservative, but also why they are thought to be and how other factors may compound the issue.

A panelist asked for clarification on how the calculation of the MOE fits into the VCCEP framework. Is this something that would be calculated after the Tier 1 hazard and exposure data have been collected to determine whether or not to move to a higher Tier? Ms. Zaleski responded that the calculation of the MOE is related more to the risk characterization of a Tier 1 assessment. EPA agreed that the MOE would be used in deciding whether or not to move to a higher tier and does not apply to the chemical selection process.

A panelist commented on the question of how to determine whether default assumptions are conservative. Many of the defaults used may be based on data developed for adults. Even if it were possible to say that these data are conservative, it would be difficult to say whether they are conservative for children. Uncertainty should be addressed. Using defaults in the case of children will be difficult due to the lack of data specifically for children. It may be appropriate to consider distributions.

A panelist asked about the use of models in this approach, and whether models examine exposure to children in their environment or the effects of exposure within a child's body by taking into account physiological factors such as breathing rate, metabolism, etc.? Ms. Zaleski explained that some of those factors might be outside the scope of a screening-level assessment. She is not aware of any PBBK models taking into account such physiological factors for

children[1]. Another panelist commented that there is an effort to develop a unified model that would start with known sources and model an individual's movement through the sources of exposure to develop an exposure history that considers physiological variables. Unfortunately, this type of model is still under development and is not immediately available.

A panelist asked whether the type of child considered for these assessments should be a median child or a 95th percentile child. Another panelist responded that the default is 95th percentile, but down the chain of commerce, a median or range could be used. EPA added that it is the responsibility of the sponsor to convince the peer consultation panel that the chemical has been adequately characterized. VCCEP is a pilot program that will be developed by answering some of the questions being raised here. Determining whether risks to a chemical have been adequately characterized is chemical- and use- specific and will be addressed through the peer consultation process. It may not be possible to answer these questions in the abstract.

One panelist responded that this question and other basic issues of the program must be answered before work can begin. Another panelist commented that as long as the data are there, we should be looking at the range of the probability and not limiting estimates to a single number.

EPA reminded the panel and audience that the Agency has guidelines for exposure assessment and a risk characterization handbook that offer guidance on this topic.

A panelist stated that data gaps are an important issue. The nature of the chemical industry and confidential information will inevitably lead to data gaps. The key to dealing with these gaps is transparency and allowing the reader to understand the information presented, how the conclusions were drawn, and make their own evaluation. Another panelist stated that the biggest problem might be lack of clarity. These basic questions should be answered as soon as possible to minimize misunderstanding and confusion.

One panelist noted that past experience indicates that screening-level assessments are over-predictive because of compounding conservativeness; therefore, the utility of these tools is questionable, and may lead to misinformation. One of the challenges for this program is to go through the anatomy of a case study and take it to another level, characterize percentiles, input

[1] After the workshop, Ms. Zaleski noted that there are some PBBK models for children, including:

M.P. Pelekis et al., 2001: Probabilistic framework for the estimation of the adult and child toxicokinetic intraspecies uncertainty factors. Poster at Society of Risk Analysis, December 2001.

M.P. Pelekis et al., 2002: Probabilistic framework for non-cancer risk assessments. Poster at Society of Toxicology, March 2002.

E.J. O'Flaherty, 1998. A physiologically based kinetic model for lead in children and adults. Environmental Health Perspectives 106, Supplement 6: 1495-1503.

J.G. Pounds and R.W. Leggett. 1998. The ICRP age-specific biokinetic model for lead: validations, empirical comparisons, and exploration. Environmental Health Perspectives 106, Supplement 6: 1505-1511.

distributions, and exposure communication issues. This is the catch-22 with screening-level assessments. Until you go through some stochastic modeling you cannot assess the utility of the screening-level assessment.

A panelist indicated that this is an issue of how the public decides to interpret risk. For example, the risk of dying is greater in a car than in an airplane, but the public perception is contrary to that. The idea that we will be able to come up with a number that will be meaningful to the public is unrealistic. The number will need to be presented with appropriate context. The risk number is very subjective; we will have to describe how it was developed, define the number, state what it represents, and let people interpret it the way they want.

An audience member asked when it is appropriate to put the word potential in front of the word "risk." Because this presentation quantifies an overly conservative number, the actual risk is overestimated. Therefore, the term "potential risk" is used to reflect where there may be risk based on the screening-level assessment.

A panel member made a formal objection to the use of the word "potential" when referring to risk, because it is redundant. Another panelist commented that there might be a difference between "potential risk" and "risk" in this case because these are pre-evaluations of risk, and not the actual risk calculation. The presenter noted that she agreed with panelist, but thought that "potential" was necessary to communicate that this is not the actual risk calculation.

A panelist noted this is an issue that has been discussed for many years. In a screening evaluation, the calculation of risk should be a simple "yes" or "no" answer, indicating whether there is need for a higher tier evaluation. Numbers quantifying the degree of risk should not be presented at this level. Otherwise, the refinement of risk shows a higher degree of risk being refined to a smaller degree of risk, and this trend can be misinterpreted.

A panelist commented that there is no chemical that can be said to pose no risk to anyone under any circumstances. Another panelist agreed with this issue, and offered to try to think of alternative terms. An audience member agreed with this issue, and suggested that the terms "measured risk" and "estimated risk" should be used. A panelist commented that perhaps this discussion of risk is beyond the scope of this workshop. EPA commented that the use of the term "potential risk" is intentional and based on significant discussion and consultation with the stakeholders on this voluntary program. The choice of these words was based on whether the volunteers would be comfortable joining the program. The focus now is to develop ways to provide clarity to the recipient of the information.

An audience member commented on a statement made in Bill Gregg's presentation, "Best can be the enemy of good," and an idea presented in Rosemary Zaleski's presentation in which we would use a margin of exposure ranging between 100 and 100,000. It is important to

identify the kind of exposure and the observable adverse effect of the exposure. Sometimes the adverse effects are considered minor, such as a minor skin irritation, and others are major, such as death. These risks need to be expressed using terms that the general public understands.

An audience member reminded the workshop that the purpose of the Tier 1 process is to arrive at a decision of whether we need to know more about the chemical. The chemicals that were selected for this pilot program were not selected based on any special concern related to their hazard to children or expectations of high levels of exposure. There are chemicals that will not require additional tiered assessments because their exposure assessment will show little or no exposure. For example, an exposure assessment of a chemical that is used as a site-limited intermediate and is never used in the environment may show there is no concern for exposure.

2.1.6 Children's Exposure Assessment

Elaine Cohen Hubal, Ph.D., Chemical Engineer, National Exposure Research Laboratory, EPA

Dr. Hubal presented definitions and approaches for evaluating children's exposure. There are two types of exposure assessment, direct assessment and indirect assessment. An indirect assessment is conducted by using available data, activity data, exposure factors, and specified algorithms to estimate the exposure. This is the most common method for a screening assessment. A direct exposure assessment is conducted by actually measuring the contact of the receptor to a chemical using personal monitoring techniques. Biomarkers are used to correlate the exposure to dose. Direct exposure assessments are very expensive and less frequently used than indirect assessments.

Dr. Hubal presented the following approach to develop an assessment. First, develop a conceptual model, and identify the potential pathways and scenarios. Then, define what algorithms, exposure factors, and data requirements are needed. The assessor should conduct a screening assessment to evaluate the range of exposures for each pathway, and then identify any remaining data gaps and uncertainties associated with the data. Finally, the assessor can design research to address these data gaps and uncertainties.

Dr. Hubal presented equations for calculating inhalation exposure, dermal exposure using both a macroactivity approach and a microactivity approach, indirect ingestion, and direct dietary ingestion. Each equation uses some combination of activity and behavior factors, microactivity data, macroenvironment and microenvironment data, physiological rates, and time to calculate the exposure.

Dr. Hubal closed her presentation by presenting challenges for VCCEP, including: identification of the chemicals, pathways, and activities that present the highest potential for risk to children, determination of children's exposure factors, development of approaches for

measuring multimedia exposures, and generation of data on multimedia exposures that may be used in aggregate exposure models.

2.1.7 General Discussion III

A panelist commented on the use of duration to estimate the impact of an exposure. There are exposure periods that impact dose more significantly than the actual period of time elapsed. For example, some occurrences of autistic infants can be correlated to a particular day of gestation during which a mother ingested a drug. The presenter agreed that this is an important point, and the assessor must consider windows of susceptibility in evaluating risk.

A panelist expressed concern over where the concentration of a chemical in breathing air space is measured within a microenvironment. The height of a child varies tremendously by age, and typically, inhalation concentrations are measured at one meter from the floor. Also, ventilation patterns in a room affect the concentration of the chemical in the air. The presenter responded that although the definition of a microenvironment is not realistic, however, it may representative. If the assessor determines that concentration is driving the estimate, then the assessor may choose to use more detail.

The panelist continued and indicated that estimating a dermal exposure using these general exposure factors will not capture special situations. For example, an infant with abraded or roughened skin due to diaper rash would have a more significant reaction to a chemical than a child with no skin rash. The presenter agreed that these are important issues to evaluate, and the assessor should identify these scenarios as exposure media are defined. The assessor is aware of the product uses, and should develop the assessment systematically based on these uses.

Another panelist noted that many industrial sponsors do not have a staff toxicologist and turn to consultants for help in completing assessments. These consultants are knowledgeable in the state of the science and know where to apply upper-bound default assumptions. In doing to, they hope to capture a wide range of exposure scenarios. For example, some models adopt an absorption value of 100% to ensure that all of the scenarios are covered. The consultants and the industry know what scenarios are appropriate to use with the assumptions.

A panelist commented that the research that is being presented here presumably will not be available for public use for many years. The presenter responded that the research that the presenter is involved in is specifically to support the Food Quality Protection Act. As soon as the data are completed, they are available to FQPA. Another panelist reiterated that by choosing 100% absorption, or other conservative input values for the exposure estimation, it is hoped that the assessment will cover the worst-case scenarios.

A panelist requested the presenter describe current child measurement research activities at the National Exposure Research Laboratory.

The panelist indicated that the past few years have been spent conducting studies to obtain dermal and non-dietary ingestion exposure data to improve the quality of these exposure factors. There is also an effort to develop methods of collecting and using data collected in the field, as well as testing protocols and pathways that have not received as much attention in the past.

A panelist commented that although information on critical windows of time for fetal development is available, similar information for children's exposures is not available. The presentation noted that environmental measurements have not correlated well to body burden, and set forth the question of whether the timing of the exposure with respect to these critical windows might be a cause. This is an issue that is being considered in current and planned studies.

A panelist questioned how the data collected at the microactivity level compares to the predicted exposure values using indirect assessment methods. There are a number of data collection efforts for which data have only recently been compiled. The laboratory is planning to compare the directly collected exposure data to the results of an indirect assessment using exposure factors. A panelist noted that there are studies where biomonitoring data were compared to indirect assessment estimates for adults, and some of the predictions were moderately comparable with the distributions. These data were not evaluated specifically for this purpose, so there may be some opportunities that have not been fully explored in evaluating these data.

An audience member further explained that the SHEDS model was first developed to simulate the microactivity approach and later to accommodate a macroactivity approach. This model has not yet been compared to measured data; however, there are efforts underway by the modeling group and the measurements group to perform this comparison.

An audience member was interested in children's activity data on playground equipment, in households, and by regions, and asked if VCCEP will consider obtaining such information. The presenter indicated that limited data related to these activities are available from the National Exposure Research Laboratory.

An audience member questioned whether these discussions have considered the audience for which the exposure assessments are intended. Specifically, the level of detail included in an assessment may be different if the assessment were used to restrict certain uses of the chemical, than if the assessment were used to ask the sponsor to conduct further toxicological or monitoring studies. Additionally, he commented that it was unclear if the peer consultation

group will evaluate whether an assessment adequately characterizes the exposures based on the data that are available, or based on data that should be collected.

The panel discussed this idea further. There is a concern that the initial margin of exposure assessment based on incomplete or incorrect toxicology will have very little value for use in a risk assessment. These data might be used, however, but it is very likely to be wrong. Another panelist expressed confidence that the exposure assessments could be accurately conducted if performed by an experienced and knowledgeable scientist. However, it is plausible that the environmental community might conclude that the assessments have a level of uncertainty, which they might find too great, due to a lack of confidence in the adequacy of the toxicological data.

Another panelist commented that a part of the VCCEP process is to test the tiered approach. OECD has tested the tiered approach and as a result developed the screening data set. This program is in the pilot phase, and the purpose is to test the hypothesis of this process. Therefore, this program is resolved to do the best assessment possible with the data available, and will be reevaluated later to address chemical-specific issues.

A panelist suggested that the purpose of VCCEP is to communicate potential health risks to the public, for which you need toxicology and exposure data. The purpose is to develop a risk characterization that can be made available to the public as well as to EPA and to identify any toxicology and exposure data gaps that exist which would need to be filled in order to characterize the health risks to children. The hazard component of conducting this risk characterization mapped out early in the process. The exposure component was not mapped out, and that is the reason for these discussions: to look at the exposure in the context of its use with risk assessment specifically for this workshop. It will not be possible to encompass all of these issues within this workshop, but there is value in recognizing where attention is needed. Additionally, when an exposure assessment is completed well, it is expected that in many cases the toxicological data will be far inferior to the exposure assessment.

The presenter commented that one could do a wonderful exposure assessment and not have the toxicology data that is needed. Alternatively, one could have wonderful toxicology data for a compound to which no one is exposed. Risk assessment requires both pieces. These discussions should not focus on insignificant issues, but should ensure that the process or framework that is used to create the exposure assessment helps identify the most important data gaps, chemicals, or need for further toxicology studies and exposure assessments.

A panelist asked the presenter how the programs at National Exposure Research Laboratory (NERL) are related to the VCCEP program. NERL has a framework for conducting screening exposure assessments, which may be useful to a sponsor. Exposure factor data for

children are being developed currently. Data that may be useful to the sponsors will be made available after analyses are completed.

A panelist noted that the quality of the data influences the level of exposure that one will tolerate. There are mechanisms to account for the type of data that is used to allow for the uncertainty. These mechanisms allow the assessor to modify the reference dose according to the type of data that are missing. The peer consultation panel will need to evaluate the data and the resulting risk characterization for whether these data are sufficient or more information is necessary.

A panelist re-emphasized the importance of integrating the hazard and exposure data. This program is an opportunity to maximize all of the information that is available. There is a concern that despite how much data are available, there will always be a request for more toxicity testing, especially when there is some question of the validity of some of the upper tier tests. For example, the developmental neurotoxicity test kills over 1,200 animals and has never been formally validated. These exposure assessments should be conducted in the most efficient manner possible and minimize unnecessary testing.

A panelist inquired about the ultimate objective and audience for these data. EPA responded that these assessments will be made publicly available so people can make more informed chemical choices, considering how the chemical is used, designed, or disposed. Ultimately, EPA does not know how these data might be used until there is better information on the children's exposures that are occurring and the associated hazards. Although many of these chemicals are extremely well studied, many are not. This is not an accident. The idea of the pilot was to see if this sort of a process might be useful in helping people understand chemicals and the choices they make about their use. The purpose of collecting these data is to inform decision making that does not equate with regulation.

A panelist expressed concern that while we may have toxicological and fetal development data for some of these chemicals in the program, there may or may not be children's toxicological data. One could make the assumption that children will be as sensitive as a fetus.

An audience member noted that the consumer products industry supports the inclusion of exposure assessment in the tiered process. The Consumer Specialty Products Association believes that exposure characterization is critical in prioritizing hazard information and in determining next steps.

2.2 Resources and Models

Three presentations were given in Part II B of the workshop, offering information on resources for completing children's exposure assessment. First, Jacqueline Moya presented the child specific exposure factors handbook. Next, Patrick Kennedy presented and discussed a list of other references and resources. Finally, Paul Price presented an overview of relevant models for exposure assessments.

*Note: The agenda shows the order of these presentations as **References and Resources for Exposure Assessments**, by Patrick Kennedy; **The Child Specific Exposure Factors Handbook**, by Jacqueline Moya; and **Relevant Models for Exposure Assessments**, by Paul Price. During the workshop, an audience member suggested that Jacqueline Moya's presentation be presented first because it was also relevant to immediately previous presentations.*

2.2.1 The Child Specific Exposure Factors Handbook

Jacqueline Moya, National Center for Environmental Assessment

Jacqueline Moya of the EPA's National Center for Environmental Assessment presented an overview of the Child Specific Exposure Factors Handbook. This handbook consolidates age-specific children exposure factors data and was developed to protect children from environmental health and safety risks. The data presented were obtained from various sources that collect exposure factor data, and are the raw data collected in all cases, except for the USDA food consumption data. The USDA food consumption data were re-analyzed for inclusion in the handbook.

The handbook contains data for the following children's exposure factors:
ingestion rates for breast milk, food, tap water, and soil; mouthing behavior; inhalation rates; physical parameters including body weight and surface area; soil adherence; activity factors; and life expectancy.

The handbooks suggests that eleven age groups contain similar data for use in exposure characterization: four age groups less than 1 year and seven age groups for children aged one to twenty years. Because these age groups are not yet finalized, the 2000 Handbook should be considered a draft.

The handbook may be downloaded from the National Center for Exposure Assessment website at www.epa.gov/ncea.

2.2.2 General Discussion IV

A panelist inquired about the status of a recommendation to NCEA to solicit pediatricians' assistance in developing age bins. A consultant was going to initiate a study to include to evaluate the existing data and age groups, and later to involve pediatricians for developing age bins; however, the study has not yet reached this stage. Another panelist indicated support for the inclusion of pediatricians in the development of age bins. The current compartmentalization does not adequately reflect the developmental variation of differently aged children. Different offices at EPA are currently evaluating the issue of age groups.

The goal of this process was to discretize children into age bins and analyze distributions of the exposure factors within the age bins, so that the developmental stage of a child within an age bin would not be ignored. There has been a great deal of effort expended trying to identify experts on this subject, and these experts may not exist. There are experts on children's behavior, but it is not in the context of exposure. This expertise needs to be developed. A panelist suggested contacting the American Pediatric Association. A paper will be published next year in collaboration with children's behavioral experts that will consider children's behavior in the context of exposure.

A panelist commented that regular Internet updates of the exposure factors handbook would be helpful, rather than waiting for finalized changes.

A panelist appreciated the NCEA exposure factors handbooks and commended the work. He further inquired if the Monte Carlo analysis guidance would be expanded. The presenter indicated that NCEA has not expanded that part of the guidance. Perhaps in the future, the Monte Carlo guidance could be expanded to suggest guidance where there are currently data gaps. For example, transparent professional judgement distributions could be used to fill data gaps.

A panelist inquired into the status of the consumer products chapter. The consumer products chapter needs additional research and work.

(The discussion was opened to the audience.)

An audience member commented that many years ago there was some discussion that photons significantly affected children's behavior. If this has not been refuted, it is suggested as an area of research.

An audience member asked the panel to further describe "transparent models." EPA responded that this topic will be discussed at length in a later presentation.

2.2.3 References and Resources for Exposure Assessments

Patrick Kennedy, Exposure Assessment Branch, EPA

Patrick Kennedy of EPA's OPPT presented the following key resources and references for developing an exposure assessment.

EPA Guidelines for Exposure Assessment (1992) is EPA's primary reference for conducting an exposure assessment. These guidelines were reviewed extensively and are widely accepted. The guidelines describe basic concepts and definitions used in exposure assessment, including intake, uptake, and dose. Guidance is also provided for developing, gathering, and using data, as well as evaluating analytical uncertainty. This document can be downloaded from the NCEA website (www.epa.gov/ncea/exposure.htm).

EPA Exposure Factors Handbook (1997) provides factors needed to conduct an exposure assessment, and consists of three volumes. The first volume presents general factors and a discussion of uncertainty and variability associated with these factors. The second volume presents food ingestion factors. The third volume presents activity factors, including consumer product use information and air exchange rates. (www.epa.gov/ncea/exposfac.htm)

EPA Child-Specific Exposure Factors Handbook (2001) provides the factors needed to conduct a children's exposure assessment.

EPA Standard Operating Procedures (SOPs) for Residential Exposure Assessment (2001) is a useful reference for conducting residential exposure assessments. The procedures were developed to evaluate exposures resulting from residential pesticide use; however, they can be applied to non-pesticide scenarios. These procedures were developed after extensive consultation with the OPP Science Advisory Panel. (www.epa.gov/oppfead1/trac/science)

EPA Science Policy Council Handbook: Risk Characterization (2000) discusses the culminating step of a risk assessment, the risk characterization. The handbook discusses components of risk characterization, including population, route, exposure, degree of uncertainty, quantitative estimates, and default values. (www.epa.gov/ORD/spc/2riskchr.htm)

EPA/OPPT Exposure Tools and Models Web Page is a useful source when monitoring data are not available. This web page includes links to obtain information on Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER), Exposure and Fate Assessment Screening Tool (E-FAST), Estimation Program Interface (EPI) Suite, Multi-Chamber Concentration and Exposure Model (MCCEM), and Wall Paint Exposure Assessment Model (WPEM). (www.epa.gov/oppt/exposure)

Clarifying questions

Panelist Question: What is the status of the HPV chemicals screening software?

Presenter Response: The development of the software is in progress. We plan to send a beta version out to selected people for evaluation, and then another version will be published.

Panelist Question: The Residential SOPs that OPPT developed with the FIFRA Science Advisory Panel were upper bound estimates that were never meant to be used in aggregate assessments. There are ongoing efforts to upgrade these SOPs so that they may be more appropriately used in true aggregate assessments.

Presenter Response: I appreciate that comment. Gary Bangs will speak further to that point in a later presentation.

Panelist Question: You mentioned in your presentation that E-FAST is a screening model and MCCEM is a more involved model. How would you classify the other models you mentioned?

Presenter Response: EPI-Suite is not designed to estimate exposures. The Wall Paint Exposure Model (WPEM) may be used as a screening-level model or as an in-depth model. WPEM has canned scenarios that may be used when there is a lack of data, but the user may also change the inputs and bring measured emission data to the model. ChemSTEER is a screening model.

Panelist Question: EPA has done a wonderful job with this. How do we ensure that different government agencies coordinate their exposure assessment efforts?

Facilitator Response: This question will be reserved for the discussion portion of this workshop.

Panelist Question: Are the recently published Risk Characterization Guidelines applicable to the HPV and VCCEP program?

Presenter Response: Yes.

2.2.4 Relevant Models for Exposure Assessments of VCCEP Chemicals

Paul Price, The Lifeline Group

Paul Price of the Lifeline Group presented an overview of exposure assessment models used in exposure assessment to improve the efficiency of calculations and to develop data that could not otherwise be developed. He also presented some preliminary recommendations for using these models.

The presentation included the following topics:

- Children's exposures
- Types of models
- History of models
- Review/overview of existing models
- Relevance of existing models

Children's exposures should be modeled differently from adult exposures because of the different behavior and physiology of these groups. Models account for some of these differences by adjusting physiological and behavioral factors based on age.

Models are created for two reasons: to economize human calculation effort or to generate data that could not be developed in any other way. Some air dispersion, groundwater, aggregate, and cumulative models are created for this reason.

Models are also often created in response to a regulatory effort. For example, dispersion modeling and air toxics modeling were created in response to the Clean Air Act, and some consumer models were created in response to the Toxics Substances Control Act. The implementation of the Resource Conservation and Recovery Act (RCRA), Superfund, and Underground Storage Tank rules led to the development models to describe the thousands of potential sites covered under these regulations, and the Food Quality Protection Act led to the development of dietary, aggregate, and cumulative models.

Existing software that can be used to analyze air exposures includes: Toxic Modeling System Short Term/Long Term (TOXST/LT), CONTAM, Indoor Air Quality and Inhalation Exposure (IAQX), RISK, MCCEM, California Population Indoor Exposure Model (CPIEM), the Total Exposure Model (TEM), NAAQS (NEM/pNEM), Hazardous Air Pollutant Exposure Model (HAPEM-MS), Simulation of Human Activities and Pollutant Exposure (SHAPE), South Coast Risk and Exposure Assessment Model (SCREAM), Total Risk Integrated Methodology (TRIM), and Air Pollution Exposure (APEX) model. Consumer models include E-FAST, ChemSTEER, Consumer Exposure Model (CONSEXPO-3), and Probabilistic Methodology for Improving Solvent Exposure Assessments (PROMISE). Site-specific models include the

American Petroleum Institute Decision Support System (API DSS), CalTOX, Multimedia Environmental Pollutant Assessment System (MEPAS), RISK*ASSISTANT, and SmartRISK. Dietary models include the Dietary Exposure Potential Model (DEPM), Dietary Exposure and Evaluation Model (DEEMS), Cumulative and Aggregate Risk Evaluation System (CARES), Stochastic Human Exposure and Dose Simulation (SHEDS), and Lifeline 1.1.

Aggregate modeling can be difficult because assuming that all exposures are concurrent may generate unrealistically high estimates. Therefore, different approaches to aggregate modeling should be considered. Current software supporting aggregate models includes Calendex, Lifeline, CARES, TRIM, MENTOR, and SHEDS.

A more detailed discussion of each of the above named models can be found in "*An Evaluation of the Potential for Use of Existing Exposure Software (or Software Currently Under Development) in a Tiered Approach to the Assessment of Exposures to Children.*" Paul Price, The Lifeline Group. December 3, 2001.

Clarifying questions

Panelist Question: You indicated that for aggregate models, the models did not do a good job of predicting the known biomonitoring levels. Can these models be tied to biomonitoring data?

Presenter Response: Aggregate modeling is very new, and we hope that these models can be validated using biomonitoring data. To date, no completed model has been compared to biomonitoring data, but there are plans in place to do these comparisons. There is some question of how one would develop models that can be effectively compared. We anticipate more work on this in the near future.

Panelist Comment: Researchers in the field try to statistically correlate environmental measurements to body burden, without a model that incorporates activities and behaviors. This simple correlation does not work. It is not that the models would not work, given the appropriate information on activities and behaviors, but a simple correlation does not work.

Panelist Question: Is there an attempt to link some of those aggregate and dispersion models to Physiologically-Based Biokinetic (PBBK) or Physiologically-Based Pharmcokinetic (PBPK) models for chemicals where that information is available? Many of the VCCEP chemicals have PBBK models for them that are quite good. These could be directly linked to the aggregate models, which could give a better sense of body burden under various kinds of exposure circumstances.

Presenter Response: This has been done with at least two of the models. Valerie Zartarian published results of a very simple, two-compartment model for chlorpyrifos which predicted urinary output. The SHEDS model was used for this simulation. They compared this output to assessment data and found that it was at least in the same order of magnitude range for the assessment. The SHEDS model is an ideal model to link with PBBK because you are modeling people. Because you have identified the person you can assign characteristics to that person, including age, gender, health status, height, weight, body mass index, and other data that can describe their physiology, which may be integrated into the PBBK models.

Audience Response: The output from the models that were mentioned in this presentation is exposure. SHEDS is the only model that has a dose estimation module, and it is very simple. The Office of Research and Development is in the process of linking the exposure module of SHEDS with the ORD Exposure Related Dose Estimating Module (ERDEM), which is a very sophisticated PBBK model. ORD is working to be able to feed the exposure profile output from SHEDS into ERDEM, in order to predict the resulting chemical level in blood and urine.

Panelist Question: By available, do you mean free of charge, or do you mean the algorithms are available for public scrutiny? Does limited availability mean that the algorithms are not available?

Presenter Response: I cannot speak for every model listed here. All of the Lifeline Group model codes are available for viewing for the purposes of validating for the copyright. Another aggregate model available is Calendex. It is the property of Novigen software. Novigen can provide information on their policies on to whom they sell software and for how much.

Panelist Question: Do the dietary and drinking water models consider elements such as thermal degradation or POTW treatment?

Presenter Response: You may enter factors into the dietary models that will account for processing, including heating, drying, and bleaching. These factors will raise or lower the pesticide residue ingested according to how they would be affected by the processing. For drinking water modeling, there is not an explicit way to account for treatment level of the drinking water. There are data on the use of well water versus a public water supply, but there are very little data to account for the level of treatment in various parts of the country.

Panelist Question: The terms “aggregate exposures” and “cumulative exposures” are sometimes used interchangeably in describing models. Please clarify how you are using the term “aggregate.”

Presenter Response: "Aggregate" refers to modeling one chemical with multiple sources and multiple routes. "Cumulative exposures" refers to modeling multiple chemicals, multiple sources, and multiple routes.

Panelist Question: I am interested in the efforts to validate these models using biomonitoring data. What are the challenges you foresee in predicting body burden from these models? As these models get more complex, it will become increasingly more difficult to use the data from an aggregate exposure model and compare that to body burden. Even if there is correlation between the aggregate exposure model and the body burden, is it possible to determine if you have accurately portioned the various chemical contributions between the pathways?

Presenter Response: This will be difficult. It is true that as these models become more complex, there are more areas in which they could be incorrect. The best way to validate modules within a model is to compare them to a monitoring test for each route of exposure in the aggregate model. Some work has been done to do this, however, more is needed.

In order to develop a model that captures variation across the nation and across ages in population, you have to look at independent and individual surveys of levels of contaminants identified in biomonitoring. The development of these models is often instigated by congressional mandate. The models were developed, and now there is a focus to validate these models.

Panelist Question: There are a number of ongoing important efforts to evaluate exposure models, including SHEDS. The Office of Research and Development conducts activities to link biomonitoring data to PBBK models. There are some important criteria to consider when evaluating these models compared to biomonitoring studies, as well as limitations, strengths and weaknesses that one should be cognizant of in doing these evaluations. For example, there are many sources of phosphates. One needs to be aware of the many potential sources when using biomonitoring data to validate a model for a particular route of exposure.

Presenter Response: I firmly believe that you should aim to do an exposure assessment without using a model. The models are there to help. If you can do a screening aggregate assessment by adding up all of the sources and have some way of segregating the sources for those that are co-occurring, and then if you can show that the sum of these doses is not a problem, then you should not pursue modeling. The models should be used only when the conservative hand calculations demonstrate there may be a problem.

Panelist Comment: I agree, and I do not think that biomonitoring will be able to validate these models in my lifetime. Most of the correlations that have been done to date do not adequately consider background and pharmacokinetics, and that is one of the reasons they rarely

match up. You should look for ways other than modeling to perform an assessment. We should take additional measurements on each specific modeling attempt, and break these master models down into components that we may be able to understand one piece at a time. By confirming pieces of the master models through measurement, we may begin to be comfortable saying the models are somewhat validated. I do not think that biomonitoring is going to get us there.

Panelist Question: Have these models ever been compared using equal input? How do you select which model is appropriate for your assessment? Are there guidelines that indicate which model might be most appropriate to use under various circumstances?

Presenter Response: Models are developed for specific reasons, and the different models have different goals. Therefore, comparing the models can be difficult. To select an appropriate model, you need to understand the purpose for which that model was created, and then understand the answer that it gives you and the relevance of that answer to the goals of your assessment.

Panelist Comment: Although no definitive comparisons have been done, these exercises are done. They just did a model comparison exercise with the aggregate models. They do these exercises to gain a better understanding what each of the models do, how they compare, and what things people are doing differently. They have done benchmarking models with NEPAS and MMSoils. Caltox did a benchmarking model that was to compare models that are just like Caltox. You are not always learning as much as you might, and it is not always as useful for people who want to use a model, but the developers are doing this exercise as part of their development path to learn more about what they are doing and how they can make adjustments.

EPA Comment: The Agency as a whole, the Office of Pesticides, and the Office of Pollution Prevention and Toxics have been looking at these models for a number of years. It has been a very long and deliberate process to compare and contrast these models because they have different assumptions and applications. We are now looking toward addressing the issues of aggregate exposures. The agency is evaluating the different models that are used in house and considering the use of other models too. A workshop was recently conducted at the National Environmental Research Laboratory where four different models were compared using the same scenario and the same biomonitoring data.

Panelist Question: There are uncertainties in the models, but the models can be very useful tools. There are methods to look at model uncertainties, such as sensitivity analyses. Could you please speak to the issue of preserving dependence on some of the variables, such as the relationship between skin surface area and body weight? Additionally, you indicated the use patterns of certain items affect exposures. How do models consider varying use patterns when developing exposure estimates?

Presenter Response: The use of numeric tools, such as a Monte Carlo analysis, requires the assumption that you have independence between the parameters from which you are sampling. Where that independence does not occur, the output from a Monte Carlo analysis will not match reality. The challenge is to find ways to ensure that independence or capture the relationship of the correlation. This problem has driven people back to focus on coherent definitions of the receptor so that as you model the receptor interactions with various sources you have a consistent definition of the receptor.

The ways to capture the correlations between activities has been looked at by trying to either explicitly model the specific correlations or by using surveys, where you have data from one person with multiple input.

Panelist Comment: There is a notion that all models should be made as simple as possible, but no simpler. That is the state of the art that we are trying to understand, especially as you get into aggregate and cumulative modeling. We are trying to grapple with temporal, spatial, and demographic differences following individuals through time. In some cases these differences and relationships are absent, so there is a substantial effort to help define these activity patterns, relationships, and issues of co-occurrence. For example, there is currently a 12-month diary survey where people are recording every pesticide they use in and around their home. These data will help us to establish co-occurrence relationships in product usage.

The purpose of the exposure assessments under VCCEP is to establish some prioritizing and decision-making mechanisms. The pesticides program has a different purpose, but there are good lessons to be learned from the pesticides program.

There are limitations with biomonitoring, and so both the modeling and biomonitoring are needed, especially in estimating aggregate and cumulative dose.

Presenter Response: To answer the question, “Why are these models so complex when you know a model should be as simple as possible?” Models are designed to handle a wide range of chemicals that vary significantly with a multitude of different forms, pathways, applications and other chemical inputs. The algorithm dealing with a single chemical and a single exposure may be quite straightforward. When your chemical comes through these models, the actual calculations that the models perform on your particular chemical are probably going to be very simple. You need to understand exactly what the model is calculating for your chemical.

2.2.5 General Discussion V

After the panel completed asking questions of clarification, the facilitator directed the discussion to charge question B1 and B2:

Charge Question B1: Are there any other resources or models that have not been identified or discussed that are relevant to VCCEP exposure assessments?

One panelist suggested that sponsors consider other government agencies, such as the FDA, DOE, DOD, and USDA, when compiling exposure information. Another panelist agreed that government agencies beyond EPA would be a valuable resource. He also noted that industry associations may be an additional potential source of exposure information and activity patterns, and that some associations have assembled expert panels that can act as a resource.

A panelist expressed concern that not all chemical manufacturers have a toxicologist on staff to complete exposure assessments. The panelist asked if any resources exist for people that will be performing an exposure assessment for the first time, or if a simpler guide to VCCEP exists for someone who is not a toxicologist.

A panelist noted that the CNO Industrial Source Complex Long-term Short-term Screen 3 is an air dispersion model that gives exposure point concentrations. This will be used quite a bit to estimate exposures for children in communities and residences, and may be an additional resource.

A panelist noted that the Office for Economic Cooperation and Development (OECD) is currently working on an R&D Tools project that will include a database of exposure assessment software. A list and explanation of these software models may be available on the Internet at http://www.oecd.org/

A panelist noted the International Life Sciences Institute is currently contemplating a data characterization effort for residential exposure factors.

A panelist noted that European models could be a valuable resource if efforts to help translate and gather some of these models could be arranged.

Charge Question B2: Are there areas not addressed by the existing models and other resources that are needed for assessing child-relevant exposures under VCCEP?

A panelist commented that the following types of models and resources are not available: models that aggregate consumer products, indoor air, and background environmental sources; breast milk pathway modeling data; models describing *in utero* exposures; and models that explicitly address child institutions, such as day care and schools. Another panelist noted that the CDC had plans to begin monitoring breast milk, and EPA was beginning to look at the PBBK models and placental transfer models.

A panelist commented that ORD, industry, and some chemical companies have begun research programs to study dermal transfer efficiencies from carpets and vinyl surfaces. Some of these data and/or algorithms might be available.

A panelist noted that in cases where canned software packages are not available, literature and smaller models describing conceptual approaches that may address components of the assessment might be available.

A panelist commented that a characterization of a child's physiology includes not only height, weight, and surface area, but also body composition, fat to water content, metabolism, the distribution of water soluble and fat soluble compounds and other parameters that vary according to the age of a child. These considerations do not appear to be addressed in these models.

A panelist noted that a cumulative assessment includes exposures from more than one chemical with a presumed common mode of toxicity. For example, an evaluation involving the exposures from organophosphate insecticides would be a cumulative assessment because it is known that organophosphate chemicals all inhibit acetylcholinesterase. PCB's and methyl mercury are both developmental neurotoxins; however, it isn't known if these chemicals are acting through the same mechanism. Therefore, an evaluation of the exposure from PCB's and methyl mercury would not be a cumulative assessment. This definition of a cumulative exposure is according to the FQPA definition. Other organizations define cumulative more broadly, including non-chemical stressors in some cases.

A recent ILSI workshop focused on the hazard portion of children's risk assessment. There were groups looking at pharmacokinetics and pharmacodynamics and the differences you would see over the course of development. Data and knowledge gaps in this area should be identified in the workshop report.

A panelist noted that the National Exposure Research Laboratory recently collected data on transfers from surfaces. Transfer efficiency data are being collected for children from different surfaces as a function of physicochemical properties. The project focused on pesticides using tracers. A significant database of this information is in the process of being published. That study is being broadened to include a wider range of physicochemical properties.

A panelist listed some areas in which additional research is needed, including:

- Transfer from surface from hand to mouth by physical properties;
- Breast milk exposure;
- *In utero* transport, which may be adequately described by PBBK, either by physicochemical properties or by straight PBBK modeling; and
- Bioavailability.

Additionally, authors of proprietary data should publish their data and make it publicly available to avoid repeated research.

A panelist questioned whether this level of information should be included in a Tier 1 screening assessment, and asked that there be some discussion of what is expected for Tier 1. There is a danger of complicating the issue in these discussions. For example, in prior presentations up to 15 age bins have been discussed for addressing physiological differences among age groups. This level of detail may be greater than what is needed at this time. It is common for a pharmaceutical company to suggest that two aspirins every four hours are the correct dose for people aged 12 to 70. These pharmaceutical doses are relatively large compared to some environmental doses. Perhaps these discussions do not have to be as detailed as they are. The approach for this program will have to be simplified in order to finish in a couple of years.

In order to limit the number of age bins for children, perhaps one could just use a one-year old child as an age group. A one-year old may capture all of the major concerns of childhood groups. Also, biomonitoring can be very helpful in addressing this issue, as it will account for some of these complex physiological details.

(Discussion opened up to the audience members.)

An audience member noted that the VCCEP sponsors are primarily chemical companies and trade associations that do not have an in-house exposure assessment branch. It may help the staff toxicologists to have a web site or another location where actual examples would identify how different people have dealt with different issues.

An audience member noted a lack of information on the validation of these models. He asked if information is available on the degree of bias in the model results as well as the direction and magnitude of the bias. The panel responded that the most apparent bias is that the models tend to be conservative. Models are biased intentionally, according to what the model is attempting to model. A screening model provides a conservatively biased estimate. In general, models tend to over predict rather than under predict.

An audience member requested that modelers consider making a Monte Carlo sampling algorithm that samples the survey data instead of the statistical distribution. This would allow the distribution to preserve information on cultural and ethnic distributions that are normally lost.

An audience member asked if EPA or the panel believes that the uncertainty in default assumptions used in the models will change as a result of these additional tests and modeling. EPA hopes to learn from the data that are collected and adjust default assumptions as appropriate.

A panelist asked if the assessor should choose a single model to conduct an assessment or more than one model, given the comprehensive list presented. The assessor needs to seek out the model that will work for their specific circumstance. Running multiple models may be necessary if more than one model is appropriate to the specific circumstance.

2.3 Example Exposure Assessments

Part II C of the workshop included four presentations. First, Patrick Kennedy of EPA's Exposure Assessment Branch provided an overview of the basic principles of transparency, completeness, data quality, and consistency. Then, EPA presented an example exposure assessment in two parts. Fred Arnold of EPA's Chemical Engineering Branch presented Part 1, which introduced the example chemical and background information for conducting the quantitative portion of the exposure assessment. Gary Bangs of EPA's Exposure Assessment Branch presented Part 2 of EPA's example assessment, which included the quantitative portion of the assessment. Then, Elizabeth Anderson of Sciences International, Inc. presented a Framework for Integrating Exposure Information.

2.3.1 Overview of Basic Principles: Transparency, Completeness, Data Quality, and Consistency

Patrick Kennedy, EPA Exposure Assessment Branch

Patrick Kennedy of EPA's Exposure Assessment Branch described basic principles of exposure assessment that are important to OPPT: transparency, characterization of completeness and data quality, and consistency in reporting key exposure assessment results.

A transparent assessment contains as much detail as is needed for a third party to duplicate the results. It contains descriptions of the completeness of the assessment, the type and source of data, key data gaps, key data assumptions, and the uncertainty.

Characterizing the completeness of an assessment conveys the scope of the assessment, describes what was assessed and what was not, and describes why certain exposures were not assessed. Characterizing the completeness of an assessment is an essential input to the process of identifying data needs. The information and analyses required for a complete assessment should be determined based on the context of the chemical under consideration.

Characterizing the quality of the data in an assessment is important. A description of the quality of monitoring, modeling, sampling and analysis methods should be provided. The assessment should also present the objectives of any studies used as well as the exposure assessment objective, quality assurance procedures, and uncertainty.

Consistency in reporting assessment results allows reviewers to easily find important pieces of information. Consistency should be balanced, however, with flexibility. EPA's nested formats allows for this flexibility in reporting assessment results.

Clarifying questions

Panelist Question: Will there be some guidance on defining "completeness" with respect to children's exposures? Some of the description of completeness here is related to manufacturing and processing, which does not seem appropriate for a children's exposure assessment.

Presenter Response: The Federal Register VCCEP notice considers parental exposures where it is appropriate. In some cases, manufacturing and occupational exposures may apply.

Panelist Question: Is the exposure to a "prospective parent" determined after identifying the hazard end points, or is that a determination in the absence of toxicity end points?

Presenter Response: This should be considered on a chemical by chemical basis.

Panelist Question: How should one characterize transparency when selecting a model?

Presenter Response: The reason you selected a particular model and used certain values could be part of establishing transparency. That kind of information is consistent with the principles of transparency.

Panelist Comment: There is general agreement on these four principles. The degree to which each of these principles can be characterized will vary by chemical. For some chemicals, we may have more complete exposure assessments because they are more relevant to the ultimate objective of making the decision, "Are the risks adequately characterized?" Also, these assessments should be informed by the hazard data.

Presenter Response: The sponsor should describe the completeness to whatever degree is appropriate for that chemical.

Panelist Comment: Transparency facilitates the reader's understanding more than it improves confidence. The intent is to be fully informative

Presenter Response: I agree.

Panelist Comment: EPA has guidance concerning transparency. Where is that?

Presenter Response: EPA has developed guidance for preparing the formats, which includes some guidance on these principles.

2.3.2 Example (Part 1): Integrated Exposure Assessment Relevant to Children's Exposures

Fred Arnold, EPA Chemical Engineering Branch

Mr. Arnold presented an example of an integrated exposure assessment for a fictional substance, Chemical C. Hazard information was not used to direct development of this exposure assessment.

Chemical C was an aromatic hydrocarbon, was slightly volatile, moderately soluble, and moderately biodegradable. It was a relatively high production volume chemical, and had one predominant use: it was sold for use as a material used to treat cracks in residential homes.

Four objectives were presented to complete the exposure assessment for Chemical C:

1) Identification of the releases;
2) Identification of potential pathways;
3) Identification of potentially exposed populations; and
4) Estimation of potential exposures to children.

Releases of Chemical C occurred during manufacture, distribution, processing, or use. A process diagram indicated that Chemical C may have been released during manufacturing and storage as both a point source and a fugitive release. Data quantifying air releases of Chemical C were not available; however, data were available for a similar chemical and formulation. Emission factors, monitoring data, and modeling data for this similar chemical were used to estimate releases of Chemical C. Additionally, a Department of Defense survey indicated that Chemical C was found in the groundwater.

Chemical C may have been transferred through the following potential pathways: Parents or breast feeding mothers exposed occupationally; transferred to the community via storage and sale of the product; residents exposed either directly or through contact with their clothing during home use; and a non-chain of commerce exposure through an environmental release from manufacturing or processing.

Based on these exposure pathways and release points, potentially exposed populations included the workers at a manufacturing or processing plant, residents living near a manufacturing or processing plant, and people who used the commercial product. Sensitive

populations, such as the elderly, children, and pregnant women should be given special consideration in the assessment.

Based on this characterization of the potential releases, pathways, and exposed populations of Chemical C, the quantitative portion of the exposure assessment was developed. This is described in Part II of this example.

2.3.3 Example (Part 2): Integrated Exposure Assessment Relevant to Children's Exposures

Gary Bangs, EPA Exposure Assessment Branch

Mr. Bangs presented Part 2 of EPA's example integrated exposure assessment for Chemical C. Mr. Bangs reiterated that this example is not necessarily a typical VCCEP chemical in that only one end-use was identified, but serves to demonstrate how the principles of completeness and transparency are included in an aggregate exposure assessment for children.

For this Tier 1 assessment, three monitoring studies and three modeling studies were used to estimate the exposure of children to Chemical C.

Monitoring data from the following studies were used:

- Breast milk study;
- Worker inhalation study;
- Post-application indoor air study; and
- Department of Defense national groundwater study.

The breast milk exposure study monitored four plant workers to determine the average potential daily exposure. Exposures to the chemical outside of the plant were not controlled. The study monitored the quantity of the chemical that was brought home on worker clothing and in outdoor air. The average potential dose rate of an infant breast feeding from an exposed worker was estimated at 0.003 mg/kg/day to 0.025 mg/kg/day.

The manufacturing facility worker exposure study collected personal inhalation monitoring samples and analyzed them for Chemical C. The results were used to evaluate exposures among the workers in the Pest-X processing facility, which uses a closed system to formulate Pest-X. No amount of Chemical C above the detection limit of 0.05 $\mu g/m^3$was observed in any of the personal monitoring samples collected (N=28) (Table 9). Therefore, an estimate of the acute potential dose was calculated using the detection limit for the air samples because no measurable quantities were observed in the samples collected. Based on the limit of detection (0.05 $\mu g/m^3$), exposure to Chemical C was estimated to be <0.007 μg/kg/day. Worker exposure is of interest because of the potential for reproductive or developmental effects.

The post-application study measured the air after product application in the home. Five homes were monitored at three feet above the floor. The monitoring results indicated that the chemical was not present above detectable levels. Therefore, the detection limit (LOD) was used for the exposure estimate. The estimated average daily dose (ADD) was less than 0.003 micrograms per kilogram per day, based on the LOD.

The DOD national groundwater survey indicated that Chemical C was detected in groundwater in over 85% of the samples analyzed at a mean concentration of 0.25 micrograms

The following modeling studies were used:

- Industrial Source Complex Long Term (ISCLT) model to model dispersion of fugitive emissions from manufacturing plant; and
- Non-dietary ingestion and dermal exposure model to estimate dermal and hand-to-mouth exposure of children in treated homes.

The ISCLT model evaluated a single site that released 100 pounds per year of Chemical C through fugitive emissions. The model estimated a maximum dose of 1.36×10^{-7} mg/kg/day to a downstream recipient.

A non-dietary ingestion and dermal exposure model was used to estimate dermal and hand-to-mouth exposures. The average potential dose rate for hand-to-mouth exposure was estimated at 0.13 mg/kg/day and the average potential dose rate for dermal exposure is estimated at 0.4 mg/kg/day.

For this exposure assessment example, an aggregate assessment is appropriate because exposures to toddlers can co-occur. For example, a toddler may be exposed to chemical C from dermal and inhalation exposure in the home, from non-dietary ingestion, and from dietary exposure in drinking water. The average daily dose is calculated by summing the results from the monitoring and modeling studies for inhalation, dermal, non-dietary, and dietary exposures for a three-year old child.

Clarifying questions

Panelist Question: Please note the degree of conservatism associated with some of the children's pathways. For example, for non-dietary ingestion there are over 2 orders of magnitude of conservatism built into those factors. The transfer from a surface to the hand is assumed to be 100%, and hand press studies indicate that this value is often two orders of magnitude lower. The event frequency is given at 20 times per hour and covers the 95^{th} percentile according to videography data. The saliva extraction factor is often less than 1 percent. Exposure duration of

4 hours per day is an upper percentile from NHATS. There is a lot of compounding conservatism in these children's exposure estimates. It is important to quantify the magnitude of this conservatism in order to maintain the principles of completeness and transparency.

Presenter Response: I agree. While these are conservative estimates, there is a lot of uncertainty within those estimates.

Panelist Question: One of the presentations referenced a "neat chemical." Please define "neat."

Presenter Response: "Neat" means pure or unadulterated.

Panelist Question: Why did you use differently aged children for different points of this assessment? For example, the breast milk scenario is developed using volume for a three-month old with a six-month old body weight. Then, when addressing air pollution exposures, you use a one-meter height for a child's breathing space, and that corresponds to a six-year old child. Then, you used a value of four hours to estimate surface contact. I am not sure what age that represents. Is it appropriate to mix up the ages of children, or should one age be used to estimate all of the exposures?

Presenter Response: I should have stated up front that we were going to look at children and not consider the adult workers, even though they are a potential pathway for women of reproductive age. The exception to this is the breast milk pathway. We used a 7.2 kilogram child, or 15 pounds, which is equal to the weight of a one-year old child.

Panelist Question: What statistic does the EPA guidance suggest for describing a "typical" exposure versus an upper end estimate? Should the typical descriptor of exposure be the median, the 95th percentile, or some other value? Should we not select this descriptor based on EPA guidance offered in other documents?

Panelist Comment: A risk evaluation uses the central tendency.

Panelist Comment: The guidance refers to what sort of person should be modeled.

Presenter Response: The example blended information from the draft guidance for aggregate exposure assessment. It says to use the methodologies of the Office of Pesticides. The exposure assessment suggests adding the higher end estimates together, however, then the estimate is more conservative. Another approach may be to take the central tendency, geometric mean, or a median value if you are using point estimates and you want to estimate the aggregate.

Panelist Comment: If there is no certain guidance on this, then I suggest that the stakeholders group discuss and define this.

EPA Response: The EPA Guidelines for Exposure Assessment and the Risk Characterization Handbook suggest that the assessor should ideally develop an estimate of the central tendency as well as a high-end estimate. Those terms are related to the distribution of exposures. That terminology is defined within the Guidelines for Exposure Assessment.

Panelist Comment: There are multiple versions of each of these documents. Our discussions are referring to point estimates. I am not sure if there is adequate information contained across all of the versions of these documents to well-define the calculation of exposures for point estimates.

EPA Response: In the Office of Pollution Prevention and Toxics screening-level assessments, we often do not have enough information to generate a distribution of exposure that would indicate the central tendency and high end estimates. Therefore, we tend to use point estimates for screening-level assessments, but ideally we'd like to have a distribution. For a screening-level evaluation, however, we would not typically use a probabilistic approach

Panelist Comment: Do the stakeholders and EPA have an agreement on how to calculate a best estimate versus the high end? At one time, EPA guidance defined it as our best estimates of the median and the highest driver factor, which is usually the concentration at the 95^{th} percentile. Would it be useful in these Tier 1 assessments to be programmatic in the Tier 1 execution of the calculation? I do not think that is too complicated. I do not think that the current guidelines provide this information, and I do not think that this example incorporated this.

Panelist Comment: You would like to define a process to determine point estimates of aggregate exposure.

Panelist Comment: It is possible to define this process for some pathways that will be considered. The guiding principles of determining the best estimate of central tendency and the best estimate of upper bound can always be used. When there are studies and data available for each of the underlying variables that would allow us to have a best estimate of central tendency for each input variable, and an upper bound best estimate of one or two key driver variables, then that would provide us with a best estimate of the upper bound. Those principles are useful and we should adopt something like that.

Panelist Comment: There are many different guidelines on calculating point estimates of central tendency and upper bound. I think it would be very helpful for the stakeholders and EPA to work together to develop an approach for selecting the appropriate exposure factors.

Panelist Comment: I concur that we need to provide guidance to the sponsors about this so there is only one document that speaks for the VCCEP program.

Panelist Comment: If you have three factors that have known distributions, and you decide to use the 97th percentile for each, then each individual factor has three chances out of one hundred. The simultaneous probability of all three of those factors can be solved with simple arithmetic. Then, if one factor is simply a point estimate, that does not change any of the odds of the other factors. The real issue is to decide what percentage you want the final answer.

Panelist Comment: I agree with that point. However, making a determination of what should be the risk level (99th versus 95th percentile) is a difficult policy issue.

Panelist Comment: What do we mean by screening assessment? Traditionally, a screening-level assessment uses traditionally adopted values. These values may be central tendency or may be 95th percentile. It is generally thought that by using these values the assessment will be overestimated and therefore conservative.

Now we are faced with the challenge: Can we do anything that is more transparent and objective than that? Are we going to try and improve upon this or use the traditional methods? I suggest the philosophy that should be used is to identify the sources of uncertainty and variability for each relevant pathway, and then make a determination whether the set of parameters is adequate to provide a known amount of confidence in the dose estimate.

Panelist Comment: It certainly will be useful to look at this issue and to try and come to some agreement on it. In the absence of that, I believe that the estimate and the level of conservatism are exactly the kind of analysis that is appropriate for a screening-level assessment, as long as assumptions are presented.

Panelist Comment: The presentation of the assumptions ensures transparency. The decision of the approach to be used for each chemical should be determined by the sponsors.

Panelist Comment: It is important to credibly document an under- or over-estimate of bias.

Panelist Comment: The assessments should include the most aggressive as well as the most typical exposures, and present these very transparently. I do not think we should be more prescriptive than that.

The previous presentation mentioned data gaps and sensitive populations. Was that reference to biological issues (genetics, age, gender) or exposure-related issues?

Panelist Comment: The example was referring to children as the sensitive population. A more specific sensitive population should be identified if the toxicological information is available to make that determination.

Panelist Question: Why was the toxicology data not considered in this assessment?

Presenter Response: The purpose of this example was to show an exposure assessment. The next step is the combination of the hazard identification data with the exposure assessment to develop the risk characterization.

Panelist Comment: I would prefer that the assessment be informed by the hazard data. Also, there are qualitative-based rationale for setting aside certain scenarios in this example. The peer consultation panel should consider these issues.

Presenter Response: That is a good point for completeness to not simply dismiss those potential routes and include more characterization.

Panelist Comment: In the example, the prospective parent pathway is identified; however, you do not know if there is a hazard or not. The assessor should identify the hazard to determine whether or not there is a parental exposure.

Presenter Response: If that information is available, then yes, the hazard information should be used in conducting the assessment. In the absence of hazard data, you also do not want to neglect exposures that could occur.

Panelist Comment: I agree that the hazard identification data should be used to make determinations about the exposure assessment. Likewise, the exposure assessment may help in completing the hazard identification so that the need for additional health testing is minimized.

Panelist Comment: The executive summary portion of the exposure assessment report would be more transparent if this section were divided into source and then pathway, indicating the expectation of risk at each point. The exposure tables would benefit from this sort of organization as well.

Panelist Comment: The averaging time that is relevant to a given toxicological endpoint should be reflected. Also, the word “average” needs to be defined and characterized.

Presenter Response: The example used acute potential dose rate and average daily dose. We tried to aim for a median on the average and 95^{th} percentile on the acute dose rate. Also, in

considering the averaging time for an endpoint, any information on product frequency of use or air dissipation is important and valid for a Tier 1 assessment if it is available.

Panelist Comment: EPA's exposure example includes the calculation of aggregate exposures for similar age groups. It is a common mistake to combine incompatible age groups.

2.3.4 General Discussion VI

After the panel completed asking questions of clarification, the facilitator directed the discussions to the charge questions C1, C2, C3 and C4.

Charge question C1: Are the basic principles of transparency, completeness, and data quality clearly described and reflected in the example and framework?

Charge question C2: Did the presentations adequately characterize the process used to develop the assessment?

The responding panelists were in agreement that this example followed the principles of transparency, completeness, and data quality, and adequately characterized the process used to develop the assessment. One panelist added that the presentation could have been clearer if it had been organized by pathway. Another panelist suggested that the example should include the source of any default values used.

Charge question C3: Are there areas where the example exposure assessments could be improved to better meet the goal of adequately characterizing the risks to children?

A panelist noted that the presentation began as a general assessment, and later focused on children. Targeting the assessment on children from the beginning could have saved some resources. The presentation should have noted that this assessment was for a three-year old child, and it should have stated why a three-year old child was selected.

Panelists further commented that it is very important to look at the hazard data. The presentation could have been more focused by using the hazard data to inform the assessment. This assessment may have been overly complete because it was not informed by the hazard data. If it were informed by the hazard data, perhaps areas that need more information would have become apparent. It should be noted that both the hazard data and the exposure assessment will be considered together as part of the package submitted for VCCEP.

A panelist suggested that it would be useful to present a statement identifying the assumed exposed population (e.g., people who experience the ambient exposure but also people who have carpet.) Different models will give a model base, sometimes including people who are

not exposed. It is important to clarify what portion of the total population an assessment includes.

A panelist commented that this exposure assessment did not seem to consider predictable misuse of a product. It would be useful to describe under what exposure scenarios misuses have occurred. It is difficult to incorporate misuse of a product and include both predicted misuses and speculated misuses. The assessment should contain a statement of whether or not predictable misuses were considered.

Charge question C4: Are there areas where the example exposure assessments go beyond what might be needed to adequately characterize the risks to children at a screening level?

A panelist commented that for the very small level of exposure presented in this example, the Screen 3 model would have provided an adequate analysis. This example, however, uses the ISCTL3 model, which is much more complex and would not provide a much better analysis of the exposure. Using ISCTL3 is more than sufficient for this case; Screen 3 could have been used.

A panelist noted that the example presents regulatory requirements in the manufacturing and processing of the chemical. If the assessment presents what the releases are in the assessment, then perhaps it could be assumed that the sponsor has reviewed and considered the occupational parental exposures. Then, the need to list the regulatory requirements is eliminated.

There is a concern that the level of detail in this exposure assessment is much greater than what will be appropriate for the majority of the VCCEP chemicals. For many of these chemicals there are over 100 processing points and perhaps a thousand products. It would be very difficult to complete this level of an assessment for each of these endpoints and each product. Perhaps in these cases the assessor could select certain products to analyze based on their relative toxicity or some other worst-case criteria. If selected products are identified for the analysis, then the assessment should state the reason why these products were selected.

(Discussion opened up to the audience members.)

An audience member suggested that an indication of the conservativeness of the estimate would be helpful in these assessments. In choosing the upper bound values versus a central tendency, the assessor should use a consistent receptor.

An audience member agreed that the assessment should contain a characterization of the most likely and the upper bound estimate, as this example did. The hazard data should be used to inform priorities. In this example, it was assumed that this chemical induced a systemic toxicity, but did not consider that there may be route of exposure changes. For example, perhaps the ingestion changes the chemical.

An audience member commented that the example indicated that the chemical is naturally present in groundwater. The assessments should contain this sort of information for the purpose of informing the exposure estimates.

There needs to be a discussion of the relationship between the toxicology and exposure needs of these assessments. Then, there needs to be some discussion on matching the toxicology data to the exposure data, and how a risk characterization should be done. This example includes an aggregate exposure calculation that adds exposures to incompatible endpoints. First, the groundwater exposure is calculated for ingestion, then the dermal exposure is calculated for blood, and then the inhalation dose calculates the dose being deposited on the lung. These exposures are being added together as if the body burden from each exposure were acting upon the same organ.

Much of the experience in developing these assessments is from the Food Quality Protection Act. FQPA has an extensive database of toxicology data developed using oral exposure data. As a result, there is a compulsion in FQPA to convert all exposures to a mg/kg/day estimate. The VCCEP program may want to consider reevaluating this convention specific to the VCCEP chemicals and develop a more appropriate method to aggregate exposures.

An audience member noted that this example was not applicable to most of the VCCEP chemicals. There should be an effort to develop a more refined example, a more representative case study, or a study presenting a data rich versus a data poor chemical. The example should focus on problem formulation and developing a conceptual model. There is general agreement on the basic concepts, as well as the equations and pathways. However, this example did not address how to use the hazard information in estimating the level of exposure, and how to consider the toxicology data. A conceptual model addressing these issues might be more useful than a chemical example that does not consider many of the chemicals on the list.

An audience member noted that in developing estimates for central tendency and upper end estimates, the assessor needs to be cautious of driving factors that may distort the exposure. A sensitivity analysis of the factors that comprise the estimate might be useful. A panel member agreed that the assessor may be able to identify what factors are significant drivers, and conducting a sensitivity analysis would facilitate understanding of that driver. Performing a stochastic or probabilistic case study would provide some insight into these drivers. While screening-level analyses are helpful for prioritization, probabilistic and sensitivity analyses allow the assessor to better focus efforts.

It is critical that the toxicity data and the exposure estimate are used together.

2.3.5 Framework for Integrating Exposure Information

Elizabeth L. Anderson, Ph.D., Sciences International, Inc.

Dr. Anderson presented a two-part framework for using exposure information in conducting a screening-level assessment. Part 1 is the selection of exposure scenarios, in which exposure scenarios are selected for quantitative analysis. Part 2 is the exposure assessment, in which the exposures are estimated for those selected scenarios.

Part 1, the selection of exposure scenarios, may be conducted using the following seven steps:

1) Organize relevant information. Focus general information into data useful for the assessment.

2) Organize your sources/create data bins. Organize the data into representative groups.

3) Identify plausible exposure pathways. Use physicochemical, usage, and hazard data to determine the exposure pathways.

4) Focus on exposures to children. Identify the pathways delivering mathematically significant exposure to children.

5) Define the receptor groups. Use age bins, sex groups, and sensitive groups to define the receptor groups.

6) Identify the exposure duration. Use the hazard data to determine whether the assessment should identify chronic or acute exposures.

7) List the exposure scenarios. Base exposure scenarios on Steps 1 through 6.

Part 2, the exposure assessment, is then conducted based on these collected data. If the screening-level assessment indicates an unacceptable level of risk, then a higher tier assessment is necessary.

Dr. Anderson presented an example to demonstrate the use of the framework. The example assessment was for a hypothetical chemical, Seussium grinchate (SGA). SGA was slightly volatile, had low persistence in water, soil, and air. It was produced in five manufacturing plants, with a total production volume of 2,200 tons per year. These plants released 88 tons per year air emissions and 2.2 tons per year water discharges. Whoville Industries operated the largest plant manufacturing SGA. SGA was used as a solvent in the manufacture of carpets, as a component in household cleaners, a solvent in food extraction, and

as a chemical intermediate. Exposure and biomonitoring data existed for SGA, as well as a hazard summary.

Using these characteristics of SGA and other supporting data, Dr. Anderson demonstrated the use of the framework to select exposure scenarios appropriate to children's exposures. The information resulting from using the framework was then used to develop the estimate for inhalation exposure.

Clarifying questions

Panelist Question: How does the assessor ensure that the worst-case scenario has been correctly identified?

Presenter Response: In this example, given the tons emitted per year and the population surrounding the plant, it is highly unlikely that the Whoville plant would not be the most aggressive source. However, this needs to be evaluated on a case by case basis.

Panelist Question: How does your "refinement" cycle compare to conducting a Tier 2 assessment?

Presenter Response: I think that there is time within the screening step to refine the screening assessment on a Tier 1 level. In this case, we used readily available data for the refinement case. In the Tier 2 assessment, you use the results of the Tier 1 characterization and conduct further studies to refine that characterization.

Panelist Question: This is a good example, it discloses uncertainty well, and characterized the statistical metrics used. Regarding children's exposure to carpet, we usually assume hand-to-mouth exposure in addition to a dermal exposure. Should your report for the Tier 1 assessment contain documentation of the refinement steps or should the report only contain the results of the refinement?

Presenter Response: We did not discuss that. I think that is important information.

Panelist Question: If the sponsor is comfortable with the assessment, and the peer consultation group indicates that refinement is necessary, is this considered Tier 2?

Presenter Response: Some sponsors may choose to refine their data before peer consultation, when they know that their exposure is artificially high. I think that inclusion of the refinement step should be at the discretion of the sponsor.

Panelist Question: Would the refining step include fenceline monitoring to check the model output? Are we considering the current and future residential development in the affected area of exposure? What proportion of homes are receiving well water versus city water?

Presenter Response: In general, if it is possible to easily obtain fenceline data to validate a model, then that would be helpful and I think it is within the scope of consideration. Regarding groundwater as a source of ingestion exposure, this example chemical was not expected to be in the groundwater. Therefore, that pathway was not considered. For other pathways, characterizing the use patterns for that chemical may provide further information.

Panelist Comment: I view these assessments as an iterative process. If a part of the assessment characteristics changes after the peer consultation is completed, then I think that the assessment should be revisited to account for this change.

Panelist Comment: You can consider zoning in your assessment to try to capture this information, but it is up to the sponsor to determine the level of detail in the assessment. I agree that this is an iterative process.

Panelist Comment: I like the conceptual framework, and it works well for this example. It is important to keep in mind the endpoints of some of these high volume chemicals, regardless of the ultimate exposure.

Panelist Comment: Under the Superfund program, the risk assessment considers current land use as well as potential land use. This is a screening-level assessment, but perhaps there should be a "worst-case" screening-level assessment.

Panelist Comment: This framework is more amenable to an analysis for a chemical with multiple or hundreds of sites. The analysis will vary by chemical. This approach is transparent, but is it complete and consistent? Can we fix this framework to be consistent and complete?

Presenter Response: This framework is not suggesting to neglect certain issues. It is trying to focus the assessment. You would not select one particular facility without consideration of how that facility represents other facilities. I think that the sponsor can complete their assessment using this framework and make it both consistent and complete.

EPA Comment: The term consistency was used to reflect how the assessment results are presented, not how the assessment should be performed.

2.3.6 General Discussion VII

After the panel completed asking questions of clarification, the facilitator directed the discussion to Charge questions C1, C2, C3, and C4.

> ***Charge question C1: Are the basic principles of transparency, completeness, and data quality clearly described and reflected in the example and framework?***
>
> ***Charge question C2: Did the presentations adequately characterize the process used to develop the assessment?***

The panel commented that the organized framework lends itself to completeness clearly and efficiently. The framework and example are transparent, and it is also complete if it is expected to assess children's exposures. If it is expected to go beyond children's exposures, it may need to be more far reaching. The framework is amenable to multiple exposures and is flexible.

The panel commented that this is a relatively simple example, and suggested presenting a more complex scenario where the exposures do not nicely overlap. The presentation example focused on inhalation, but the complete example, including all of the considered scenarios, is presented in the paper "A Framework and Case Study for VCCEP Exposure Assessment."

A panel member commented that VCCEP is not the "Super Comprehensive Environmental Protection Act." The VCCEP program is designed to provide data to enable the public to better understand the potential children's health risks associated with certain chemical exposures. Many existing regulations reflect upon risks to children. VCCEP does not include everything that could possibly could be an issue, but rather it is intended to focus on those issues that we have not yet been able to examine, to quantify the dose, to determine if the existing toxicology base is adequate to develop an informed decision, and whether we need to collect more data to develop an informed decision. For the sake of simplicity, it is important to remember the central theme, which is to gather data to make an informed decision of whether or not this chemical deserves more attention.

A panel member questioned whether a refined Tier 1 assessment is automatically a Tier 2 assessment. This decision should be left to the sponsor. The sponsor should be allowed to take the Tier 1 assessment as far as they feel is necessary. In the case where the peer consultation group identifies some data that was not used in the assessment, there is a question of whether the assessment should be returned to the sponsor for refinement or if this is now Tier 2.

Charge question C3: Are there areas where the example exposure assessments could be improved to better meet the goal of adequately characterizing the risks to children?

A panel member commented that the level of effort in this example is beyond what is expected for Tier 1.

Charge question C4: Are there areas where the example exposure assessments go beyond what might be needed to adequately characterize the risks to children at a screening level?

The panel commented that the framework should be flexible and allow the sponsor to include this level of detail, if desired. When there is no data for a sponsor to use for their chemical, the sponsor may choose to do a monitoring study prior to completing the Tier 1 assessment, or the sponsor will complete the Tier 1 assessment by indicating this data need. Monitoring may be beyond Tier 1, but it is a good idea if sponsors want to do that. When there is a data gap, the sponsor can move to the next tier and indicate that data gap, or the sponsor may choose to model the exposure.

(Discussion opened up to the audience members.)

Several audience members commented that the framework and example were very helpful. However, it was disappointing that the dispersion model was refined but not the receptor model, which could have been easy to refine. The presenter responded that in preparing the example, the refinement of the dispersion model reduced the exposure concern sufficiently so that no further refinement was necessary; however, a sponsor may consider further refinement.

An audience member noted that the justification for de-selection of an exposure scenario was based upon two studies in the example. The presenter stated that whether or not this is sufficient for the peer consultation panel for de-selection will depend on the chemical and the weight of the toxicological evidence.

An audience member noted that given that a screening exposure estimate will be conservative and therefore artificially high, it seems that the sponsor would always want to further refine the estimate. An initial screening estimate that is overly conservative may indicate an exposure that is above a level of concern. Further refinement of the assessment may reduce the exposure to below the level of concern. This further refinement may occur years after the initial exposure level is published. It is a challenge to present that process and the reduced estimate to the public. The presenter agreed, and stated this is one reason a sponsor may choose to conduct refinements within Tier 1.

A panel member noted in the example that a certain reference dose is used as a benchmark in completing the Tier 1 assessment. If the reference dose was decreased by a factor of ten, how would the Tier 2 assessment proceed? The presenter clarified that in this case, the first step is to reexamine the existing data to ensure that it is used correctly. The second step is to collect any additional data to validate the existing data. Then, if the sponsor is confident in their assessment and the new reference dose, the sponsor should begin taking steps to limit the exposure of that chemical.

An audience member commented that the level of completeness for these assessments needs to be evaluated based on the intended audience. If the intended audience is EPA and a scientific review panel, then it may be assumed that presenting the science behind the assessment is sufficient and complete. However, if the intended audience is the general public, then the sponsor would need to add information in the record explaining issues such as the conservativeness of exposure estimates and the reference dose.

An audience member noted that both of the examples presented today include chemicals that have few uses. Some chemicals have thousands of end uses and hundreds of facilities. The presenter explained that the framework was specifically designed to accommodate chemicals with multiple end uses and facilities, through the use of grouping in the second step. A panelist added that in the case where the chemical has thousands of potential exposure scenarios, the sponsor should use best professional judgement to select the most problematic scenarios. For example, five scenarios could be assessed.

An audience member noted that in some cases, the chemicals are very data rich. A decision has to be made about how much information should be included in the Tier 1 assessment. The panel responded that the sponsor should be able to limit the amount of data needed to address children's exposure based on the toxicology data. The sponsor is expected to bring forward readily available data under Tier 1 and to identify future data needs. If the chemical is very data rich, then perhaps the sponsor could proceed to Tier 2. This program does not mandate that the sponsor create new data under Tier 1.

A panelist summarized that in these discussions, it seems the chemicals are being distinguished as either being data rich or data poor. Perhaps the sponsors will want to regroup in six months to discuss generic approaches after they have begun their Tier 1 assessments. Each assessment will be chemical specific, and these examples could be tailored to many of the chemicals.

2.4 EPA's Draft Exposure Summaries

Part II D of the workshop included two presentations. First, Nhan Nguyen, Branch Chief for EPA's Chemical Engineering Branch, presented an overview of EPA's draft exposure

summaries. Jennifer Faraci of the Chemical Engineering Branch then presented a completed example of the exposure summaries.

Because the following two presentations are closely related, questions of clarification were asked with a single session after both presentations were completed. This portion of the discussion is contained within Section 3.4.2.

2.4.1 Overview of Draft Exposure Summaries

Nhan Nguyen, Chief, EPA/EETD/Chemical Engineering Branch

Mr. Nguyen began the presentation by noting that "exposure summaries are still work in progress although they do convey EPA thoughts at this point in time and that one of the purposes of the workshop is to get input from technical experts."

Mr. Nguyen's presentation consisted of four parts: 1) what are exposure summaries?, 2) why do we need exposure summaries?, 3) overview of the exposure summary formats, and 4) summary.

Regarding parts 1 and 2, Mr. Nguyen stated that "exposure summaries are standard but flexible formats or templates that can be used to present and/or summarize exposure assessment results" and that "exposure summaries can provide a roadmap for conducting exposure assessment and a snapshot of exposure assessment results as well." He also emphasized that the formats "are not intended to be prescriptive but rather to provide a suggested flow of information only**."** He provided a number of reasons why exposure summaries are needed including: a) EPA believes there is a need for consistency on the reporting and presenting of exposure information, b) a consistent format will allow readers to more easily find information, c) a consistent format can also help exposure assessors/preparers in developing exposure assessments and summarizing exposure assessment results, and d) it is important to characterize the completeness and quality of exposure assessment results in a transparent manner and exposure summaries will facilitate that.

Mr. Nguyen then presented the four exposure summary formats developed by EPA for the VCCEP program:

- General Information Summary;
- Summary of Exposures and Releases;
- Summary of Monitoring Evaluations; and
- Summary of Modeling Evaluations.

The General Information Summary format includes information about the submitter, chemical identification information and properties, production volume, and uses. This format

also includes an executive summary section to summarize the information provided in each section, and how this information relates to the use activities. The executive summary section contains subsections on characterization of completeness, synthesis of key assessment results, discussion of uncertainties and data gaps, summary of data collection effort, contents, and a summary of exposure results table.

The Summary of Releases and Exposures format contains information specific to a certain activity or use listed in the general information summary format. This format contains sections on volume of the chemical associated with that activity, the form and concentration of the chemical, and a general process description. The format also contains a section for users to summarize where the chemical is being used in the activity and environmental releases to the various media for both on-site and off-site releases.

The purpose of Summary of Monitoring Evaluations and the Summary of Modeling Evaluations formats are to summarize data from each monitoring or modeling study used in an assessment. These formats provide sections to summarize basic information (e.g. modeling study objective, key model inputs) on the modeling study, results and uncertainties, and references. The information contained in these summaries should enable a third party to duplicate the assessment results.

Mr. Nguyen then described the concept of nesting. He mentioned that the general information for the package is contained in a single summary, the General Information Summary. Then, for each activity identified for that chemical, a Summary of Release and Exposure is completed. This Summary will compile all of the monitoring and modeling data identified for that activity. Because there may be multiple activities for a chemical, there will be multiple summary of release and exposure. The Summaries of Monitoring and Modeling Studies are completed for each activity, and one summary is completed per study. Therefore, there may be multiple summaries of monitoring studies completed for a particular activity because there may be (and probably will be) multiple activities for a chemical, there will be a multiple summary of release and exposure.

In summary, Mr. Nguyen highlighted a number of points made during the presentation including: 1) EPA believes there is a need for a consistent format in presenting and reporting exposure information, 2) standard but flexible summary formats will promote consistency in presenting and reporting exposure information and ease in reviewing exposure results, 3) EPA's suggested exposure summaries are a work in progress – they are not intended to be prescriptive but rather to provide a suggested flow of information, and 4) exposure summaries should be designed to characterize the completeness and quality of exposure assessment results in a transparent manner.

Mr. Nguyen's presentation slides are available on the EPA Chemical Right-To-Know website at http://www.epa.gov/chemrtk/expagnda.htm by clicking on the title of the presentation in the agenda. The instructions for filling out the summary formats and the descriptions of the data elements are described in EPA's "Draft Technical Document for Characterizing and Presenting Summary Chemical Exposure Assessment Results".

2.4.2 Example Format (for an Integrated Exposure Assessment Relevant to Children's Exposures)

Jennifer Faraci, EPA Chemical Engineering Branch

Ms. Faraci presented an example of an integrated exposure assessment prepared using the example summary formats. Chemical C, the fictitious example chemical described in previous presentations, was used for this example exposure assessment summary. The summary formats are intended to provide a consistent method for reporting the exposure assessment results. In this particular example, five activities or pathways that present a potential for exposure were included. The executive summary section of the General Information format explains why these particular activities were included, and why certain other activities were not included or were not relevant. A key component of the example summary formats is the nesting design, which allows multiple data sets, including both monitoring and modeling data, to be presented in an organized format for each particular activity or pathway. In the example presented for Chemical C, not all summary formats are filled out for all five activities. Only the relevant or available data is included, and in general, EPA does not intend for each blank in the formats to be completed for every exposure assessment. Specific examples using Chemical C were presented by Ms. Faraci using the formats for the common types of summary data that would typically be included in an exposure assessment, including Releases and Exposure, Monitoring Evaluations, and Modeling Evaluations.

The General Information Summary includes chemical C descriptions as well as an outline of the information contained in the subsequent summaries. One General Information Summary was completed for the Chemical C assessment.

One Summary of Exposure and Releases format was completed for each of the five activities outlined in the General Information Summary: manufacturing, processing, indoor residential crack and crevice treatment, "unassociated with specific uses," and "various uses." Ms. Faraci presented an example summary of exposure and releases for the processing activity.

To demonstrate the use of the Summary of Monitoring Evaluations format, Ms. Faraci presented a monitoring study supporting the manufacturing activity. The study examined the exposures of infants of working mothers to Chemical C through breast milk. The objectives of the study, sampling and analysis methods, quality control information, and results were presented as part of the example.

To demonstrate the use of the Summary of Modeling Evaluations format, Ms. Faraci presented a modeling study supporting the indoor residential crack and crevice treatment activity. The study modeled the exposures of children from the dermal and hand-to-mouth pathways. The objectives, model properties, key model inputs, results, and uncertainty information were presented as part of the example.

Ms. Faraci's presentation slides are available on the EPA Chemical Right-To-Know website at http://www.epa.gov/chemrtk/expagnda.htm by clicking on the title of the presentation in the agenda.

Clarifying questions

After both presentations, the facilitator asked the panel to submit clarification questions to the presenters. Due to the content of these discussions, the panel questions and presenter/EPA answers have been only minimally edited.

Panelist Question: I gather this is an exposure summary of key studies, right?

Presenter Response: Exactly. Again, this is going to be a professional decision based on what data are deemed to be relevant and important to that particular assessment.

Panelist Question: You mentioned that you do not have to include all the data if you do not feel that it is necessary, but then again we have to explain why we did not include all the data. Where would you include the information that states what data you are not using?

Presenter Response: Actually, I think that it is in the format.

Panelist Question: It should be in the summary of releases and exposure, and I think…

Presenter Response: I think that information can be included under the Summary of Releases and Exposure, but also in the General Information Summary initially. That would be an excellent place to describe in a narrative fashion how the assessment was completed, what things were intentionally left out, and an explanation of why they were not necessary for inclusion.

Panelist Question: But I do not think I see a specific spot. You might want to consider adding that.

Presenter Response: Okay.

Panelist Question: How detailed should the explanation be for why data were not included? That is a question that the stakeholders have.

Presenter Response: TERA will be the reviewers in this case, and they will determine the adequacy of the originator's rationale to exclude certain information.

Panelist Question: This is sort of like, How clean is clean? How complete is complete?

Presenter Response: The originator should provide a statement containing the rationale for excluding the data as well as a basis for those statements.

Panelist Question: In the area of clarification, is this survey form viewed as being the doorway or an optional tool? I am asking the question up front, because if it is an optional tool that people can choose or choose not to use, then I have one set of comments. If it is the doorway, that this or some variation of it is the format that everyone will be required to use to participate in the process, then I have another set of comments.

Presenter Response: As I mentioned at the outset, I think our perspective is that we believe that there needs to be some consistency in the way that exposure information is presented and reported. I mentioned that the federal register says that the EPA should work with stakeholders to develop robust summaries that sponsors can use to present and report exposure information. TERA will look at this information and determine if it is transparent enough and if the data is of sufficient quality to characterize the risks to children.

EPA Response: This is a voluntary program; it is not prescriptive. Nobody has to do anything. EPA believes that it would be helpful if people did converge around a common format because it would make it easier to look across chemicals; it would make it easier to evaluate chemical information. But there is not a requirement as part of having signed up to use a particular format or a particular template. Unfortunately, in the arena of exposure, as you know, there are not the nice neat road maps that you have on the hazard or toxicology side (although those folks would tell me they do not have road maps either.) We are attempting to move toward something that would help people achieve consistency. We were hoping to get ideas, suggestions, and examples from you all that might make it possible to improve upon this example. This is the way EPA does it, but that does not mean that EPA's way is going to be found adequate, or overkill, or underkill by the peer consultation process that TERA will be managing.

Panelist Question: Some of these forms and the approach look very similar to the PMN process. Did you borrow part of that approach?

Presenter Response: PMNs was one reference that was considered. There are other references we looked at, including EPA's exposure assessment guidelines, and other references as well.

Panelist Question: The forms look very similar as well.

Presenter Response: Somewhat similar, yes.

Panelist Question: The guidance for these forms seems well documented and seems to have a lot of instruction. The process for selection of the model child or subject, however, is unclear and looks non-prescriptive. We have seen an example where a three year old child was chosen for analysis. Why? Why not select an infant or an adolescent? If the chemical has endocrine effects, why not an 11 year old? I do not see any instruction on how to pick a model or a subject or a type of exposure. Additionally, there is no context for how these data are applied to a whole group of children at a variety of stages and settings. The age of the subject used to complete the assessment should be appropriate to the exposure pathway.

Panelist Comment: This is a Tier 1 screening, so we are basically looking at the upper bound worst case with the data we have. That is what they were demonstrating and what Betty Anderson was demonstrating. We cannot go beyond the state of the art, and maybe that is what you are asking, although I am not sure.

Panelist Comment: No, that is not what I am asking. I think there are data that are not being used. For example, if chemicals are found in a group of foods, one could look at the foods that the chemical is most likely to appear in, and then look at what age children are most likely to eat that food. We might find that a five-year old is most likely to be exposed to that food. But then we might find that the chemical is also found in the carpet, so we look at a different child for carpet exposure, because we will look at the child who spends the most time on the carpet. There are specific children for specific kinds of exposure, and those data are available.

Panelist Comment: I think that will be done, if needed. What we are sort of heading toward is evaluating risk for a child from age 0 to 21. You are almost adding up age ranges to get the risk for "Child" all the way through. I am not sure that can be done. I do think that the sponsor's will look for the best data to use to do this.

Panelist Comment: I think your point is important, but I think we will be doing that. If you look at Elizabeth Anderson's assessment yesterday, she had a variety of age groups that she tried to account for. There is still some professional judgement in an evolving state of the art, as to how we differentiate behavior and physiology into age bins or into some continuum. So I think we will be trying to do that - looking at differential food consumption, juice for example

over different age groups, versus the carpet crawling infant. I think we will be trying to do that, even as part of a screening-level assessment.

Being in the business of scientific information management, I appreciate what EPA is attempting to do here, and I think some of the suggestions are very good. I would not want the assessors to lose sight of what they are doing by having them fill out a lot of forms, although I do not think that EPA is necessarily trying to impose that. There is some flexibility and this is a voluntary program, and I view this documentation process as part of a learning curve and pilot process. As you said, the peer review consultation will also provide some feedback, perhaps.

One of the things I found difficult to synthesize in the overall assessment was the uncertainty sections were found with different pieces. Maybe there is an opportunity for an overall uncertainty discussion that would bring things into context.

Panelist Comment: I think that both the EPA presentation and Elizabeth Anderson's presentation have done a pretty good job of trying to keep the age ranges straight and using age-specific exposure assumptions to come up with age categories and estimates of dose that are age consistent. Betty had the advantage that she considered toxicology up front and was able to pre-select the ages she was interested in. EPA did not, so they focused on the one or two age groups that had the highest potential exposure. In the end, they would have to go through a separate exercise and look at the toxicology and determine which age groups were appropriate. If it were the three-year old, then the exposure assessments will work just fine. If not, we may have to go back and look at another age group and evaluate exposures specific to them. I think we are fairly in tune, and I have been, on the whole, fairly impressed with both presentations as doing it fundamentally right.

I also wanted to add that I think this is a very sound presentation and sound format for capturing and documenting the information in a way that is open and enables someone in the future to go back and validate and document the basis for the decision and the basis for the data. I am very attracted to the summary forms as a tool for documentation. EPA needs to be applauded that they've captured the right elements and have the right boxes for putting the data together.

Panelist Comment: I think the question of "How complete is complete?" and what constitutes adequate justification for excluding certain exposure information is really important and something we should clarify. An issue that we spent a lot of time on yesterday, "Can the hazard information direct your exposure assessment?" and it was my understanding that the charge to the VCCEP sponsors is to present a complete picture of all the existing exposure information in Tier 1, and also to bring forth all of the existing hazard information into Tier 1. Since many of these chemicals are data rich, there might be extensive human data,

epidemiological data, data that far exceeds the HPV SIDS battery. I am concerned that sponsors might take animal toxicity tests that have a lot of uncertainties built into them and have not even been shown to be relevant to the human condition and use that information to exclude exposure pathways.

Panelist Question: On your summary of exposure results, when you have done the aggregate, you have done it for "Child." I would suggest that clearly that if we have children of different age groups then that would be taken into account when you do your aggregate. I am wondering why you did not do an aggregate of the adult applicators, and also can you tell me how, under chronic exposure, the aggregate for the child comes out to 0.46?

Presenter Response: We said that we made a scientific best judgement in trying to tease out which would be, from a deterministic assessment, the pathways of greatest exposures. We did an assessment of adult exposures to cover the fetal exposure but we did not aggregate it. There are other potential pathways of exposures in other occupational groups, but certainly other pathways that were not included. We tried to present the high end or most exposed age group or groups. We assessed the exposure to infants and small children.

Panelist Question: But with the adult applicators, you might have different toxicology data associated with a different level of exposure/dose-response for your end point of concern than for what you are concerned about for children. So the toxicology data could be different, so therefore you need to keep the adult applicators and you cannot look at exposure data without taking into account the hazard data.

Under the chronic exposure, you have the aggregate exposure for the child is written as 0.46, and I do not understand how you get that number.

Presenter Response: That has just been handed to me. It looks like it is a typo. Try 0.063 and see if that is right.

Panelist Comment: I think this approach has tried to be complete and look at a lot of different information, but I think what it may have lost in some of that is again some of the relevance to assessing children's exposure for a specific circumstance. For example, if there were an up front step on integration (e.g., data binning and identifying the important pathways) then that would help to focus the level of detail that would be needed for some of the other pieces of the assessment. That type of up front integration would help focus on the child relevant pathways and the specific age groups that might be important to consider.

2.4.3 General Discussion VIII

After the panel completed asking questions of clarification, the facilitator directed the discussion toward the charge questions for these presentations.

Charge question D1: Are there additional core, broad information categories, or data elements that should be included in the exposure summaries to present and characterize exposure assessment results of relevance to children?

Charge question D2: Are there core, broad information categories or data elements that are not essential for summarizing and characterizing exposure assessment results and thus should not be included in the exposure summaries and format?

Charge question D3: Are the exposure summaries useful and adequate for consistently presenting and characterizing the completeness and data quality of the exposure assessment results, in a transparent manner, for risk assessment purposes under VCCEP?

Charge question D4: Is the guidance document that describes the exposure summary formats and the data elements sufficient? Are there any limitations in the exposure summary format or the instructions that affect the user's ability to adequately characterize the quality and completeness of the data in a transparent manner?

(Due to the content of these discussions, the discussion has been only minimally edited, and the comment-answer format is used to preserve the structure of the discussion.)

Panelist Comment: As we have talked before and what I hear from sponsors, people are expecting to do a knowledge-based development of information at the screening level for these submissions, and as we talked yesterday, those ought to be informed by hazards. Sponsors really need to cast a wide net, so to speak, relative to developing readily available information. That means looking at uses and releases that are relevant to children. At a first pass, those are probably qualitative with any available data on monitoring. Then sponsors go through a process as part of developing the exposure assessment to prioritize the relevant exposures and do a thorough and complete job of describing those indicating those that are believed to be *de minimus*, and a rationale for doing that. I think the above can be described in a straightforward and transparent discussion as we saw in the summary discussions. Both of the examples that were shared yesterday were excellent narrative descriptions of what was done, what was not; what was set aside, what was not.

To turn toward the suggested forms, I appreciate Mary Ellen Weber's comments about sponsor's choice in this matter. I think ultimately, these will be taken

through a peer consultation process. I am sure that TERA will put together a group of highly respected scientists who will be able to take a look at those. Those people will be the ultimate standard-setters, relative to both the big picture and the intimate details of the entire range of the assessment.

However, when I look at these forms as backup, it really is a highly structured approach. That is the implication. I hear the comment that they are flexible and not prescriptive, but that is not the message I see as I look at these forms. There is an implication that every box must be checked, and there are twenty or thirty pages of boxes in the blank forms. As was described the other day, many of the chemicals that we are dealing with have hundreds or thousands of production sites, or sites where they are being used, and products. I end up seeing this as being a massive amount of detail that isn't going to provide what we want, which is a focused kind of an effort on really understanding the exposures that are relevant to children. They do not focus on the looking over your shoulder at the hazard data. It is not really screening level. This does not look like a screening-level approach. It goes substantially beyond the UEIP, which we've discussed in great detail in previous stakeholder meetings. I do not think that the goal in these assessments is really a complete materials accounting. It is reminiscent of how I feel coming up to April 15 every year about to face the U.S. tax code. It presents a major challenge. I do not think the perfect mass balance, the perfect checking of all these boxes really is necessary for the kind of assessments to make the decision about the adequacy of characterization. It leads to an implied tyranny of completeness. Clearly, sponsors will be putting together scientific documents that will be reviewed by a scientific panel. These documents really need to be fully referenced. I think the idea of summarizing key studies that are critical to that assessment make a lot of sense. If you take a look at the Sciences International document that was presented yesterday, in the back of the document there are six or eight critical studies that were critical to the relevance of exposure to children, which were backed up with kind of a standard scientific summary. Perhaps that provides us with an example.

But really looking at this form, it does not support the flexibility that I think makes sense in a pilot program, sort of on a chemical by chemical basis, and it does not really, if required to be used, it does not support the learning experience that I think we are looking for in this pilot.

Facilitator Comment: I think we heard EPA's comment previously that this is not a requirement; this is an optional tool, but the hope was that it would be useful enough with feedback that people would want to use it.

EPA Comment: I am not sure we got the message adequately across. The whole concept of nesting is that you can pull out the leaves that you do not need, the things that are not relevant. I would also refer back to the general summary. That is where you set the stage for talking about what kinds of things in general were worth focusing on and what kinds of things

you did not think were, and what sort of uncertainties were particularly relevant to what follows. In the nesting you just get progressively more detailed, as appropriate. It is not meant to be a mindless exercise where you have to check all the boxes, nor is it meant to suggest that every one of the summaries and every one of the activities is relevant for every chemical. In both Elizabeth Anderson's and EPA's presentations yesterday, the effort was made to find the representative worst case, because we are all talking about Tier 1 and the entry level. If you've got hundreds of uses and thousands of plants, obviously you can't cover every single one. But you probably have an informed professional judgement as to what would be the bounding kinds of data analyses and data gathering that you might want to do. This example is presuming you went through that thought. You already figured out what is important and what is not, and you have got your data, you have got your information, and now you are presenting it. It is not suggesting you do that for every use, every facility, and every product.

Panelist Comment: I think what will happen in practice as industry starts preparing these, they will start getting a better sense of what is important. I agree it should not become overly prescriptive. There will be, as we go through the peer consultation process, I assume a lot of feedback from those reviews in terms of what the peer consultation panel thinks is important or unnecessary. It is important that information gets communicated back saying, "We do not need as much information in this area," or "This particular piece of information is really critical to our evaluation." Of course that will differ for different chemicals and exposure circumstances, so after we run through a few of these in the pilot program, I think we can come back and look at the forms and say whether we are hitting the mark in the way that they should. In practice, I think that is how it will work.

Regarding Charge Question 1 and utilizing other government agencies as resources for exposure information: I think early on in the process it is important to ask the other agencies who may have regulatory purview over various uses of the product, "For this particular chemical, what input do you have at this point in time to the exposure circumstances that are being considered?" I think we can save a lot of trouble in the long run if we do that. I think we can say explicitly to CDC, "Do you have any information from your NHANES study, the National Report Card, that would be relevant here?" Having biomonitoring data in blood or urine is a good way of integrating a lot of complex factors that are going to go into children's exposure. Ask these questions up front, and they may even be stimulated to generate some information on their own if they already have methods in place. If it is a methods development issue, it will take CDC a long time, but if methods are in place, then they might be able to generate something quickly. I think it is important that this is done early in the process rather than at the peer consultation time.

Panelist Comment: I wanted to summarize what I think of in an exposure summary. I think that the sponsors might want to consider at least looking at the information that is provided and the exposure summary that was presented and decide what they want to keep what they do

not want to keep. You can always modify it; make your own form, or your own format. I definitely agree that we have to consider hazard, especially with the hazard data rich chemicals. We should consider that data first to determine what exposure routes we are going to evaluate, and then stress that these summaries are summaries of key studies. Consortium have been discussing this (question): how much should we summarize of key studies? Then you have to explain why you did not include the other studies. For some, maybe it is just that they are too old, and then maybe provide more detail for newer studies for which you feel the data just are not usable. I do feel there has to be some sort of exposure summary before you do the exposure assessment, but you may not have to do it this way, as EPA said.

Panelist Comment: There are a lot of useful elements in the forms. We need the opportunity to go through a few case studies and the peer consultation process to nail this down and make it more meaningful. Also, I agree with the comment that we have found gold nuggets of information hiding in various places at other regulatory agencies. That process, whether it happens before or as part of peer consultation, is a very useful thing to think about.

Panelist Comment: I think I understand EPA's objectives for developing the formats, and their desire to get a consistent flow of information. As we move over the years of the process there is going to be a great deal of information. This provides an easier way for reviewers to actually sit down and not have to fish out the important things that they are looking for. I also believe that these goals can be met with other approaches as well. We are talking about a suggested flow of information, and I think that is the intent here. That is the intent that I have heard. It does not necessarily mean that it has to be a checking-the-box type of format to achieve that same kind of consistency and flow. I think that any attempt to capture perfect information by having this kind of format, where if you do not have it, that is okay, you can put "not applicable," but if you do, and asking all the questions that could be answered, I think what that does is it can lead to confusion in the information flow itself. I think it is difficult to weed out the information when what you are looking for is what is important, because you have to sift through a lot of things that were not looked at that could have been summarized in a sentence or two.

I think there should also be consistency with other efforts. There are several organizations looking at this same issue and trying to achieve the same goals as far as consistency and flow, and the Agency knows what those efforts are. We have been communicating for a couple years now on these things. I think these things all need to be consistent. I would not want to see one format for this program, another format for another program, and yet a third format for another program. If these things are already being considered at significant levels, such as the OECD, then perhaps we should take a look at how this information can be captured in the other existing types of approaches. As long as the information and the flow are there and the critical elements are there, I think that is what is most important, not necessarily what the pages look like, but actually, that flow of information. There are definitely efforts out there that are underway, and I think we should be looking at those because

a great deal of progress has already been made in those with multi-stakeholder and other types of groups, so it might be a good idea to look to those things.

Things like the executive summary, when I look at that I scratch my head and think, "We are summarizing a summary?" So, I would assume that this information is not going to appear in a vacuum, that sponsors should have the flexibility to summarize. If they want to do overall summaries of things then they should be given the flexibility of how they want to put those things forth as long as the critical flow already exists to summarize the individual studies.

Panelist Comment: I just think these are very good tools, and we have to separate what is going to be an end product, something that would be included in the final document that goes to peer review. I think this could be a good collection tool that is a good way to organize data and I would not be overly compulsive about completeness as you work through. For many of the chemicals, as Elizabeth Anderson showed yesterday, it is going to be kind of a funnel, this might help organize how you choose what goes where at what point in time. It seems to me you might begin to fill out many of these on a number of different studies, and then you go through that and it might help you select which are the ones that appear to be most useful, or you could assess strength of the various components in the various reports and studies. You can view this both as an end product as well as a process document that might be helpful to sponsors to begin to organize the data. Then those that you choose you have already completed so you do not have to do it a second time. It is another way to look at this that is not quite not so onerous as, "Boy, every one of these that we start we are going to have to finish and its going to have to be included." As you work your way winnowing the critical elements, some of these may go into a file cabinet somewhere but not be sent to peer review.

I also think these kinds of summaries are very helpful to peer reviewers who are going to come in relatively cold to the data and the topic. Frequently all you have is a reference, now you have got to go back to the original document, and the amount of work you have to do, you may want to do that, but I think these would be very helpful to streamline the peer review process. If every chemical has a uniform format, you know where to look for all of the supporting documentation for that chemical and the same location for finding information.

Panelist Comment: I was trying to determine if I was in the public or with a company whether I would want to receive this document and then say, "I understand: the goals have been accomplished." I am looking at page 11 and 12 of Jennifer Faraci's presentation. Do we envision that one might see twelve or fifteen exposure scenarios presented and documented in these exposure submissions? Or do we see five examples that represent what has been concluded to be the most likely highest exposure scenario for children. This really does feel to me like a PMN plus an emphasis on children. I see this thing as being much more specific. There is a lot of other

regulation and legislation out there. Do not we really want to know the five (I am picking five) scenarios that we think provide the highest exposure to children for the use of that chemical, and document that, and then go home at that point? And then furthermore, if someone wants to punch it into the computer and they want to know about methylene chloride and children's exposures, these five scenarios come up, the calculations might be available, and then everyone knows its okay to use methylene chloride in whatever product it is used in.

EPA Comment: We do not know what the right answer is. We are looking for guidance from the panel.

Panelist Comment: You are asking us?

EPA Comment: Yes.

Panelist Comment: All right. That is what I would like. I do not have any idea if any of this is consistent with what you all have talked about the past couple of years, but as an exposure risk person, with this global question, "Are my children at risk?" and somebody told me that company X has thought about the inhalation exposures from their plants, exposures of the mother and possible risk of the off spring, and the two or three major commercial uses, I'd be satisfied. I thought that is what the spirit of this was. Like I said, this is a PMN plus. People can do it if they want to, but it did not seem to be central to the theme we are trying to tackle here.

EPA Comment: Actually, I think what you are talking about is going to be a major to-do out of this conference, specifically, risk communication. This kind of a format may be applied to one example or a thousand, or two or three, and who knows how many are right. But whatever examples or data sources you choose are going to have to be systematically justified as being the right five, or the right three, or the right fifteen. That, I think, is the kind of detail or rigor that grandma does not want or need. But I do think a very major task for all of us is going to be figuring out how to appropriately, and hopefully with some consistency and cohesiveness between EPA and the environmental community and the industry community, to communicate accurately the kinds of concerns or non-concerns associated with chemicals after they have gone through this process and indeed, as they are going through it. We have a great deal to lose, as an Agency, if risks are inappropriately exaggerated in the minds of the public. We have, I think, as much to lose as industry or anyone else. I think we are going to be spending considerable time talking about how we can do the communication part. This is an organizing vehicle, and it does provide a way, not the only way, for documenting the basis for focusing on particular areas that the exposure assessment may have focused on. I do not think a priori we can determine whether the right number is three, five, or fifteen.

Panelist Comment: I do not know if it is three, five, or ten, but I do not want to know about the other twenty that were thought about and considered less important, I do not think,

quantitatively. I might want to see a list that says I thought about this, this, this, this, and this, and we concluded the doses were less, and here are the five we thought were our drivers. Again, I could be wrong, we can make this as big as we want. But, when I started to see requests for what is the personal protective equipment, and the plant, and what are the national production volumes, and all that stuff that does not seem relevant, and it seems like this is something you could muck around in for a long time, if you wanted to jerk somebody around with all this kind of data. It is so hard to get your hands around, compared to the theme. There are plenty of regulatory ways that this information is communicated. It seems like it is outside the scope of this particular project. Again, I could be dead wrong on this.

Panelist Comment: The goal of industry and EPA are the same. This form may not show it, but I think Mary Ellen Weber was saying what you are saying. We want to report or summarize those significant pathways with significant risk that drive the risk. This is risk based. I understand what you are saying - there is information in here that befuddles it. This is just a start, and they said that it was draft. Yes, it does look PMN-ish, but I really think that we are not arguing apples and oranges; we are just arguing different apples. That is where they and we want to go.

Panelist Comment: It seems like this is a comprehensive form trying to cover a lot of bases. I think that it is possible to develop this kind of format where you are talking about a flow of information where if you have a circumstance such as limited data, the reviewer does not have to wade through a bunch of different pages of what could be erroneous information because, by golly, that box is there, so somehow it has to be addressed. There is also a visual aspect that I think some folks feel uncomfortable with where you fill out a form and 7/8 of the form is "NA." This does present a visual thing upon first glance that could be misperceived as "These people obviously did not do their homework, and decided to go the '>NA' route and take the easy way out." There are formats out there that allow for this maximum flexibility while keeping the integrity of the flow of information. Again, I urge the Agency to consider the work that is already underway, and I think everyone around the table is willing to pitch in on an effort to come up with a format that we all, at the end of the day, can at least grin, if not smile about.

Panelist Comment: The forms include some pretty basic information that is necessary, but also include much additional information. I like the forms for the exposure modeling and monitoring summaries, but the other forms include detailed information that may not be relevant to an assessment. For example, the earlier forms that included detailed manufacturing diagrams and each single point of potential emission to the environment. This detailed information kind of takes the focus away from children. If you are assessing environmental emissions, then I would suggest the use of some broader, general categories, such as an estimate of overall environmental emissions without all the detailed check boxes. You would consider the key emission sources, or estimates of overall emissions that are important for a facility or consumer product, for example, rather than having many categories that do not apply. That would be a more useful approach.

The nesting approach, I understand this was meant to be very straightforward, but when you are looking at each type of industrial and manufacturing operation and then each type of use under that, it makes it difficult sometimes to bin together exposures that are important to bin together. Perhaps if you have a product that has the same type of contact that occur in an industrial setting and in a residential setting, you want to bin it. If dermal exposure can occur in both areas, and that is important to your assessment, then you want to integrate that information. And you might assess each separately, but you need some type of up front information to look at the important groups together.

Panelist Comment: Regarding the executive summary: An executive summary or a plain language summary up front is critical for transparency and clarity, and can even be used as a risk communication tool. VCCEP is part of the chemical right-to-know program. These summaries are going up on the web. The audience includes the general public and they are not going to sift through all these technical documents. Having something right up front that says, "Chemical X is used for these purposes. These are some of the important properties. These are some of the pathways we looked at. And this is what we found." I think that would be very helpful in terms of risk communication and clarity.

Panelist Comment: I agree, the executive summary is important for the exact reasons you said. You could, however, pull it way up front. There is going to be this complete package that I envision, with the following components: toxicity or hazard dossier, exposure summaries, and then the communication pieces that describe each of these pieces and how they were derived in a very straightforward and brief manner. This should tie the two together.

EPA Comment: There may be a confusion here between the report summaries, the summaries of individual underlying data reports, and what you would be presenting at the top layer, which is the exposure assessment. The exposure assessment is the integrated document, and it will have a partner, the hazard assessment. The hazard assessment will then be combined into the risk assessment. There is supposed to be that umbrella, the general summary that goes above these formats. These formats were just supposed to be how to summarize individual approaches to exposure data.

Panelist Comment: That is helpful clarification. So, these forms were a suggested way of organizing information, documenting it, sort of in the background. Would these forms be made publicly available? Is that still in discussion as to what would be made publicly available?

EPA Comment: It is my understanding that this whole program is public. In other words, everything that would be submitted is going to be public. However, the observation that the average person is not going to want to go into this nitty gritty is correct. The first thing that you would see presumably is the overall risk characterization, and then you would see a risk

assessment, then you would see the hazard assessment and exposure assessment with the robust summaries associated therein. I haven't designed a web page yet, but I would think that if I pressed a button I would want to look top down. Other people may like bottom up.

Panelist Comment: Yes, I agree. We are talking about tools. The forms I see as a tool, a possible tool that someone could use. Clearly documentation has to be made available to the peer consultation group to make sense of all this. We are still in the optimization mode in that regard.

Panelist Comment: Is this meeting an appropriate time to make a proposal for an alternative? I am not critical of what has been presented, I like it. I like it a lot, from a thoroughness standpoint. If you want that kind of information, then that is the kind of information you should have. It is well organized, and it is the way it ought to be presented. I'll tell you what I thought you wanted before two days ago. Our group just completed a fairly exhaustive assessment, I think the first one on children's health, involving CCA, which is a good test run for seeing how one might do this. If I were the public, I have eight items I would like to see regarding children's exposure, not in any rank order:

- What is the inhalation exposure via a manufacturing point source? Just for curiosity, I would want to know what the companies think their highest exposure is to children. This would be just a numeral, and then you would do something with that numeral.
- What is the dermal exposure due to in home use?
- What is the inhalation exposure due to in home use?
- What is the ingestion exposure due to food?
- What is the ingestion exposure due to incidental exposure in the home?
- What is the ingestion exposure due to incidental exposure outside the home?
- What is the dermal contact outside the home?

There may be a couple others. Just that statement, and then an answer at the end. Then you can scroll down under each one and figure out how the calculation is done and what assumptions were made, the location, and the reference supporting each factor. Then people could make qualitative evaluations about that data. You could push another button and there will be some margin of exposure against a toxicology end point. Then there will be a summary that says, based on that simple comparison, this warrants this or that, or does not warrant anything. Very

easy to get through those. You could have all this other information in an appendix, but as a consumer or a risk person, I probably want to know these simple things.

Panelist Comment: I agree. This is a tool, and it is one of many tools. Industry presented a critical pathway approach, and that is the way that I think it should go. EPA is doing it by operational source, and then to monitoring and modeling. There are parts that are not critical to assessment of risk for a child, are not needed, and confuse the issue. It confuses aggregation of risk and various pathways. The executive summary that came out of this summary was essentially used for the Chemical C exposure assessment. This is done by operational-type things. I would like to see it broken out by pathway, critical pathway, and that sort of thing. You could do it by operation, manufacturing, this pathway, processing, this user, this product, but I think the pathway approach is the clearer way.

Panelist Comment: (Panelist presented an overhead) I am making this very brief presentation in response to one line on one page in the forms. That was the statement, "Is the model available?" and then the side columns it said "Open" versus "Proprietary." I do not think those two are necessarily exclusive. I would like to walk through the four or five issues related to the issue of availability of models. I think there is a continuum of availability for models that you need to somehow capture in here. They go from the extreme of models that have never seen the light of day, they're in the bowels of DOD or DOE and are very secret, to models that are fully available and open; the code is open and anyone can modify or use them.

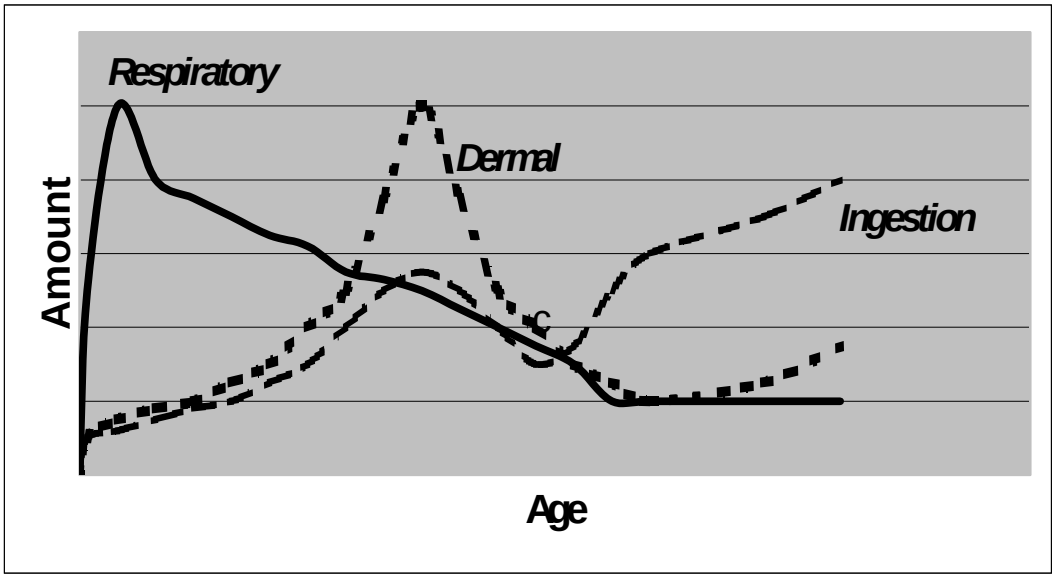
I.	Private models:	Limited release and circulation, either due to cost or developer's choice
II.	Widely available	The model is available for a cost, but the code is closed. Excel and Word are examples. If these models are universally used, well tested, and well understood, then I think they qualify as open even though the code is unavailable.
III.	Available:	Code is available, but not modifiable.
IV.	Open	Program is free. Code is free and modifiable.

Categories 1 and 2 can be labeled "black box." Categories 3 and 4 are truly open software. That is, you can verify exactly what that program is doing and why it is doing that. Category 2 software, I think is acceptable if it has been appropriately evaluated and widely used. Categories 1, 2, and 3 can be copyrighted and therefore, proprietary. That is not the same as a closed piece

of software. Only category 4 is truly open. Finally, all types of software can be validated. You can take any of these models through a validation process.

We need to have a process for capturing all these different software ideas of copyright, validation, proprietary, open and closed, and they all overlap. There needs to be some attention to capturing the system and deciding inside of this process which types and categories of models are appropriate.

Panelist Comment: To highlight what was just said, one thing that allows a great deal of flexibility in any format are text fields. It allows for the same flow of information while allowing the user to summarize what they want in a sentence or two instead of going through a couple of pages of boxes to be checked. They can briefly describe in a meaningful way what Paul just described regarding the differences in models and in the availability of the algorithms and things of that nature. In regard to the general reporting, people are asking how is this going to be meaningful to the public and the reviewer. The OECD in the SIDS process has a flow of information that is internationally recognized. They have the up front executive summary that is the initial profile. They have an initial assessment report, which has a placeholder for exposure information to be annexed in, and then there is the toxicity dossier, which are the hazard data. In this program we would include that exposure piece, which would be the summaries of the exposure. I do not think we need to reinvent the wheel here. There are existing things that we can tap into. The ultimate thing on this is flexibility. It is important to maintain consistency and the flow of information for the people that have to or want to read this, but I think that can be done with existing types of formats that are out there that are based on these text types of fields.



Panelist Comment: (Panelist presented an overhead) I am going to try to be more explicit about my problem. This responds to the comment about if I just know how toxic this is in terms of air or diet or whatever, this is what I want to know. I wish it were that simple. Let me show you an example. Let's take a couple of exposure pathways. Let's take a dietary or ingested pathway.

For the ingestion pathway, there will be some period of non-dietary ingestion but it is still ingestion. Then it is present in some foods that kids eat, increasingly as they get older, and so it goes on. Then, there is some air pollution, and that goes down to a stable level as you get to be an adult - it starts high, and then works its way down through time. There is another type of exposure, dermal contact, which goes up for a while due to carpets and then goes down, and then goes up again in lawns or playgrounds. The question is, all of these individually, at any one time, are below some toxic level. When you add them together, they add together in different amounts at different times. How are you going to get at the 1 year old, 2 year old, 5 year old, 8 year old, and 10 year old with all of these different kinds of exposures? I do not see where any of this modeling is going to get at this kind of an answer. Maybe no one wants this kind of an answer, but from a clinician's point of view, that is what I am interested in.

Panelist Comment: I do not think that is going to be a problem. Our problem is that we can't answer the question, but we can do the math. I had eight exposure opportunities, and then the sum for those, and you are right, it was a grand mean. I picked the high spots, showing the ADDs. You could do it other ways. I think the one you would like to see is:

Age	Total Dose (avg)	Age Specific RfD
0-2	x	
2-4	x	
4-13	x	
13-70	x	

The problem is you would like us to have RfD or acceptable doses aggregate from all pathways for each of these boxes. Maybe that is what will happen down the road as this process evolves. There would be no problem coming up with a mean dose and cumulative dose for each of these categories. The only thing is there is nothing to compare it against, at this point. We could present that data that way, and then as the toxicology data comes in, then we can compare it.

Panelist Comment: I would suggest that we can do age-specific exposure estimates. I agree that we need to use broader categories of endpoints we assume are equally applicable to different age groups, but be that as it may, it is a source of uncertainty. We still have been routinely trying to discretize different age intervals. I encourage you to think we are further along that learning curve than you might think. We are also trying to follow individuals through time now. If you really want to try to understand intra- and inter-person variability and correlations - everything in life is correlated in some way or another, and many of the correlations are not significant enough so we can ignore them effectively - but we are doing calendar based modeling now, where we are trying to follow individuals through time. We've got numerous experiences now with children, with adults, occupational, residential, and school settings. We are moving forward.

Also, I like the idea of more of a receptor-based orientation for communicating the results of the assessment either to technical audiences or non-technical audiences. There is a lot of experience with consumer product companies, consumer research centers, in dealing with interfaces with consumers. It is much more intuitive for them if you talk in those terms rather than in the historical source to dose construct.

Panelist Comment: The finances behind this, and the effort that it takes to answer those eight questions I suggested, even on a Tier 1, with documentation that would satisfy everybody, is a fairly pricey journey, not including the hours by the client to figure out what it is they want done, after they've done God knows how much work it is to figure out where all those sources are and quantifying them and all that. It is a $100,000 journey after you have collected a lot of the information, by the time that you document it, do the calculations and the like. You multiply that by the number of potential participants, it gets to be pricey. That is not counting all the gobs of people time prior to that. That is why I've tried to minimize to get to the heart of this because it is so pricey to assemble this kind of information.

Panelist Comment: I think it is important to simplify it as much as we can, but for the first few its going to make sense to err on the side of presenting too much information rather than too little. That is only going to slow down the process if we err on the other end as it goes through peer consultation, people are going to be disappointed and irritated if they do not have all the information they would like. It is important to make it as simple as possible, not only for the public but also for the scientist who would be conducting the peer consultation.

Regarding the uncertainty, it is going to be very important as we go through the peer consultation process with these. We need to do as good of a job, and as complete of a job as we can on that. There is obviously going to be a lot of uncertainty when models are using children's scaling factors, regarding if any models are used about not having physiological constants that are appropriate for kids in these sorts of things. I believe EPA is

doing some of this, maybe through NCEA, developing some of those physiological constants for children and I know we are doing it in the national toxicology program to try and get that information on the table early on so those models can be applied early on and not later.

(Discussion opened up to the audience members.)

Audience Comment: I am sympathetic to the eternal struggle between scientists having information and data and regulatory community wanting to sort it out in simple, describable criteria, or check off summaries, or whatever. However, I spent fourteen years at EPA and I was part of this struggle. I think we have to be very careful when the science gets forced into criteria or boxes, that we do not 1) lose the integrity of the data (when we check something off, you can lose the integrity of the data behind what is being checked off) 2) If we are not careful, we are creating a diffuse landscape of checkmarks that may not have a relevance to what is important when we want to focus on exposures to children. I warn against those two things: losing the integrity of the data and creating a landscape of information that is diffuse.

Yesterday, when I presented the seven steps in the framework, it was precisely to try to organize the information so that we walk through sequentially the seven steps. I told you that this resulted from two very diverse sets of chemicals and children's exposure assessments we had done, where we had literally hundreds of facilities and hundreds and thousands of products. To deal with this, that first step is to gather all of this relevant information and start to focus on the profile for that chemical. What are the manufacturing processes? What are the products? What are the facilities? And so forth.

The second step is to recognize that while you may have hundreds and thousands of sources, children can only be exposed by certain means. If you have got the TEAM data then maybe it does not describe everything, but you can spot check to see if one exposure source contributes a disproportional amount of a chemical to room air. This was not so hypothetical - it was actually a composite case study from the two circumstances we worked on. So you can spot check the data you have. Children can only be exposed through certain means: food, water, ambient air, and indoor air. You organize those hundreds of thousands of sources into manageable data bins where you might have information. For a lot of these chemicals, we will be surprised at the amount of information we do have. Then you are not dealing with all of these sources. So if you check a box saying "Hundreds of thousands of sources" and you do not organize it, it is going to be an unmanageable and diffuse set to put out to the public.

The third step we were proposing is to assemble all of the plausible pathways, so you know what they are. But then in the fourth step we start to look at the information that we have and we start to narrow. In our case study we went from ten plausible to five. This was a composite, hypothetical chemical, but it was developed from two real world studies. So you go to the five, and so you are not just checking contributions that may be

contributing in the fourth or fifth data point to something that is important. I had the ten micrograms, and then I had some contributions at 0.02 to 0.03. I do not think any of us want to see a check list that just checks off, "Yes, we have all of these contributions," when some of them are really trivial. It confuses the issue.

And then we move to focus on the exposures to children, so then you start to narrow more. I see a logic that is needed here. If you do not sequentially move to focus on what is important and not focus on a lot of things that are not important, then we are going to be lost in a landscape of complexities and data.

On to the fifth step, which are the receptors. What are children's activities? How can they contact? What does the toxicity data tell us about what receptor groups we should be looking at? The sixth step is to use the toxicology data to inform duration and frequency, and the seventh is when we finally get to that exposure scenario that is important.

I can tell you from the two studies we have done, we did not find them very expensive. This brings a simplicity or logic to what I think could be an otherwise unmanageable landscape of information. I think also that when we start to distribute data to the public and to the consultation peer committee, we need to organize it and focus it. Otherwise, we are going to have such a body of data, it is going to be uninformative.

Audience Comment: I wanted to comment on the two presentations this morning and the organized format. I understand the need to have a systematic logical approach to putting the data together, but I think that one has to recognize the phenomenal difference in the data availability for the compounds on these lists. This might preclude what some people might call a consistent approach. Just three areas that come to mind.

- Process Diagram: For a large refinery, petrochemical or chemical complex, there is no way to fit a process diagram on one page. You could simplify it, but I am not sure that would address the purpose of what someone was thinking of. And at each one of these plants, you do not want to be accused of being non-transparent.

- Trying to account for where 100% of your chemical goes: If you have limited products and customers, that might be possible, but then they have customers, and they have customers, and so on. You can try to do the best you can, but again, you do not want to be accused of not having a transparent assessment. You also do not want to get bogged down in that part of the assessment. I think you want to get to the bottom line part, as to what are the risks here.

- The monitoring studies summary: This is really disconcerting to someone who understands the incredible amount of data out there. There have been air toxics

studies from the last fifteen years from Burlington, Vermont to Chicago to L.A. There are these photochemical smog areas that are going out and getting data on these aromatics every single day and have been for many years. There are multiple studies in all sorts of microenvironments. The idea of having to actually fill out a sheet of paper stating why you did not use a certain study - you do not want to get bogged down in that. For some of these data rich chemicals, we will need to depend on some informed reason and judgement with out getting caught up in the details on why a study was not used.

Audience Comment: Two questions:

1) Will these forms be available on EPA's website for us to use?
2) Regarding confidential business information, in looking at CBI, there are some things that industry considers CBI that are suggested to be presented in an open format. Most people consider confidential:
    (a) sales volume, in particular sales volume to any particular customer;
    (b) price of the product; and
    (c) manufacturing process description.

Within the recommended format, there are two of these three things that are being asked for. If these things cannot be aggregated as an industry, they probably will not be presented unless there will be some CBI provisions for us. There has been a lot of discussion over the past few days in terms of some of the products on the list have wide uses and wide volumes, and I would think that the ability to aggregate that information is going to be relatively easy. But then there are other products, like those that I represent, that have very specific uses and one or two customers, and it may not be possible for us to do an aggregation. I would throw that out as a question. I do not have the answer.

EPA Comment: I will make an attempt to tell you a little bit about some activities that I do know of and perhaps others can say more. I am on the advisory panel for the Alliance for Chemical Awareness. One of the major issues there has been the concern about confidentiality, antitrust problems, how does one aggregate and how do you get information out. At one of our meetings, a person made a presentation from a trade association indicating that there is a committee that is working on these kinds of issues. There is a recognition that there are real barriers in terms of sharing information from one company to another because of antitrust, but also sharing information that is company specific because of market share and other kinds of concerns. I do not have the answer on how that will be done in the context of VCCEP. I do suggest that API, ACC, SOCMA, and others might want to get together and deal with this, because there are ways to construct generic scenarios, generic approaches to this that would still meet the spirit of this program. Fundamentally, it is a right-to-know program. That does not mean we need to know things that are irrelevant to the issue of risk characterization of children.

Panelist Comment: One of my colleagues with whom I have worked very closely served on that committee. One thing that was found is, obviously, there will be situations that arise where there are no answers; where the information flat out may not be able to be publicly available for legal reasons, and hopefully those will be the exception rather than the rule, and we think that they are. They are working pretty hard to develop mechanisms for information sharing through third parties and things of that nature.

Audience Comment: This is just an observation and at the end I have a suggestion. I'd like to make the observation first and direct it to EPA. As a result of listening to, looking at, and thinking about the presentations from EPA this morning, and looking at the written material, I am really struck by the contrast between some of the words I hear and the strong message that is conveyed with the form approach. We have heard some of the EPA speakers use the words "flexibility" and "ease of use," but what I see is rigidity. I have heard the words "non-prescriptive," but what I read in here is "fill in every blank on all the forms and track every molecule." So, I do not really understand the contrast. What I think it is, is that EPA has missed the mark here - missed the mark by a wide margin. In fact, I do not even think they are in the ballpark, if I may mix metaphors. EPA is looking for a form approach that is innovative and geared toward producing results in a manner that is consistent. We are not going to get there, if we are going to use this approach that is proposed here where you have to find and track every molecule. That is my observation, for what it is worth.

I am appreciative of the panel's suggestions, particularly as a result of pulling the panel together. I think there has been valuable feedback given to EPA on this matter. That is, this is to be a child-focused approach. This is not souped up PMNs. This is not redoing UEIP. This is something different. This is a pilot program, focused on children. I particularly want to urge EPA to think about the presentation that Dr. Anderson made the other day, on how to approach the universe to really focus on children, and then the suggestions by Dr. Paustenbach and others at the table today, which is to say "Let's make this child-focused." Let's ask the questions, what are children exposed to by these various pathways, and then provide the science to support that. And then finally, one last comment. Scientists have been engaged in the publication of information for a long time now, and there is a consistent format that folks use that seems to work pretty well and peer reviewers are comfortable with. It is what every one does when the publish a manuscript or a paper. That is:

Introduction:	What you are looking at and why.
Materials and methods:	What you have done and how you have done it, in details so others can judge the value of those methods.
Results and Conclusions	
Discussion:	What does it mean?

That is a road map, the biggest road map you could follow in the scientific process. There will be other details. Maybe section 3.1.2 is dermal exposures to children. But that is the road map. It is the table of contents. And it is not check the box fill in every form. Thank you.

Audience Comment: I was trying to sit here and integrate what we have heard the last couple of days, both in the EPA presentation of the example and in Elizabeth Anderson's presentation. It struck me that Ms. Anderson had one way of organizing it that was particularly helpful here, which was that first one would look the appropriate exposure scenarios, and then one would examine those exposure scenarios. In looking at the EPA form, I think that the forms look more to the evaluation of the exposure scenarios itself, the second stage, and not so much at the analysis of how one chose those exposure scenarios. It strikes me that the peer consultation will be equally interested in both of those components. You might have done a great job of analyzing a scenario but you might have chosen the wrong scenario. Both components are important.

Even if we were going to use the EPA forms for the second half of this, that is, looking at the exposure scenario, I suggest that the forms may be too focused on data and models and not on the underlying analysis. It seems to me that we are interested in what is the analysis. For instance, it is unlikely that you actually have a model or data that directly fits. You are going to have to pick and choose and try to make something of it. I would suggest that taking the EPA forms, the summary of monitoring evaluations and modeling evaluations, change that to essentially a summary of the exposure scenario, and you try to get the summary of the analysis which would include perhaps monitoring and modeling data, but perhaps more than that. You move away from the idea that the exposure assessment is just data and modeling. It is really data, modeling, and this something else, which I am calling analysis. I think we are missing that, in particularly in cases where we have not a whole lot of good models or data, the emphasis should be on the analysis and this needs to be captured. So just to summarize, I think we need a front end, which is choosing the exposure scenario, and it may have to be in narrative form. But it also has to be transparent. Secondly, to focus on the analysis rather than just on the data.

Audience Comment: It has been pointed out a number of times the problems with the checkbox approach. These problems can be exacerbated by the tendency to take the numbers in a summary table that are footnoted with all the caveats of how that number came to be, but often those numbers take on a life of their own without the footnotes and caveats. I think there is an example of how this can happen and the problems that it can cause if you look at page 12 of Jennifer Faraci's presentation. This is a table that includes acute exposure estimates and chronic exposure estimates, and every box is checked. In most of the releases, especially those that were done with monitoring, there is a chronic calculation that comes up with a number that you would expect is lower, since you do not apply the pesticide every day, you do not have workers working every day. However, when you get down to the childhood exposures in inhalation, dermal, and non-dietary ingestion, you see that the chronic exposure is the same as the acute.

What this tells me is that there really was not a modeling or separate analysis done on the chronic exposures. Or, if there were, this was a house where every morning at 7 o'clock the pest control van came in to spray the whole house, and that happens through the lifetime of the child. In my mind, that is not worst case, that is worst fantasy or bad dream. But that is not caught here in that the first thing you would do in looking at this is assume that there is an actual, realistic chance of a chronic risk at that level of Chemical C.

My feeling of a Tier 1 assessment is that in this table, that should have been blank. If there was not a separate calculation of a reasonable worst case or most likely chronic exposure would be, that should have been blank. In a later Tier, you might pick a reasonable worst case and take that through and do a separate analysis.

EPA Comment: I am not sure there is as much disagreement as some people think there is. I think what has happened is we are talking about apples and oranges, to get to the audience observation about disconnects between words and deeds here. I do not think that it is inconsistent to endorse the idea of triaging or the idea of a framework or the pyramid as Elizabeth Anderson presented yesterday. Nor is it inconsistent with our values to have an overall analytical piece that explains why you focused on what you focused on, how you got there, and what do you think it means. And yet have, underlying that, which is sort of nesting or tiering, what ever you want to call it, a supporting documentation that gets relatively detailed about the things that you chose to do. I am not sure that the kinds of details or format that we have presented is necessarily the perfect one, but I do not think that it is inconsistent with the concept of flexibility that different chemicals may need different analyses, different scenarios and different levels of sophistication in the data. And that is to be informed by the circumstances of that chemical, and among the circumstance of the chemical certainly is the toxicity. I am not sure there is a huge disconnect here.

I do think that there may be some fairly strong difference of opinion that once you have gotten down to the point where you are focused on a specific scenario or pathway, how much detail you want to put in codified format such as checking boxes as opposed to free form text. I would argue you need both. You certainly need the text to explain whether you are in the middle of the box or on the edges, but on the other hand, it is very helpful to have a way of codifying some information too. So I do not see the huge disconnect. I do see a difference of opinion in terms of what a format would look like once you have decided what you want to study.

Audience Comment: I have three points that have been largely anticipated by other remarks, so I will try to be succinct. First, when I read the written materials and saw the presentations, it did strike me as very prescriptive, so I think your remarks clarifying this are extremely important. It is very important that they be captured in writing in the write-up of the proceedings. Because they convey a different message. For example, in the working draft

technical document says on page 1 that the formats are not intended to be prescriptive, but on the second page, that document says, "It is imperative that exposure assessment results be reported in a consistent manner." Now, I view that as prescriptive. On the same page, it says that, "an exposure format should be completed for each- and each is underscored - each separate activity associated with a chemical. Manufacturing, processing, and each of the various uses." I looked at this, and I thought it was very prescriptive. I thought that in a pilot program, obviously, completeness, transparency, and quality are key principles; but I think you want to encourage innovation and not prescribe up front the one way to do the assessment or the one way to present the results. I really view your remarks as quite different from what has been presented, and it is really important to capture that. And that way the sponsors and EPA management and staff and peer consultants will have a common ground on that point.

EPA Comment: If I may clarify my remarks, the EPA examples and frameworks were based on a presumption of absence of toxicity information. Therefore, there was a presumption that one did need to be comprehensive in looking at all the various potential exposure scenarios, including starting at manufacturing and working one's way through. If there are circumstances where a sponsor feels a subset of that is fully adequate and fully explanatory, then it is imperative still that they tell you still what they did, why they did it, and how they did it. So, I think that word "imperative"- we are not necessarily suggesting taking it out, but maybe modifying a different part of the guidance, if you will.

Audience Comment: Just to state my position, I do not think the format should be made imperative, although I think it is a tool that people could consider using. I do not think it should become, as a panel member said yesterday, "a rule" that people have to follow. I think the notion that a format be completed for each activity without some ability to make choices about what is important would be wrong. I think your comments earlier really clarified that, which is why I think it is important that record supercede what is in this document.

Yesterday the point was made that for many of these chemicals a bottom up, layered approach would not be practical, and I want to emphasize that. We have chemicals in the pilot that have been through the OECD SIDS review under EPA sponsorship and have been determined to be of low priority for further work. That does not meant that further work is not appropriate here, but it does illustrate to me why sponsors need to be to able to make reasonable choices that can be documented and explained in writing, as you said, about why they focused in some areas and other areas were considered relatively unimportant and certainly not appropriate for completing the summary formats, etcetera.

A lot of people have talked about the integration of hazard and exposure, and I would just like to illustrate a couple of places where that would work well. In the EPA example, there was an estimate of a dose from fugitive emissions, and that estimate of dose was about a thousand fold below a microgram per kilogram per day, which is extremely low

dose. In the very next sentence, the document said more work is going to be done. I understand that you were not using hazard information, but to me that is a perfect example of where a sentence inserting reference to hazard information might tell you that no further work needs to be done. It is a good decision point.

The second thing is when you discuss uncertainty, often I think you discuss limitations, so the transfer coefficient was based on adults rather than children, this or that, but I think those could be put into context again by reference to hazard. So if your exposure assessment puts you a thousand fold below some relevant health benchmark, then you can complete your statement of what the limitation are and it does not really matter. Or, if your exposure assessment puts you very close to that relevant health benchmark, a very different conclusion might be reached. So that is another place where I think the integration would be helpful.

Audience Comment: I just want to reiterate the concern for a bottom up approach versus a top down approach. For many of these chemicals, as we have been discussing, they are used in so many places that a bottom up approach is just totally infeasible, and the forms are not really amenable to that.

Also, I want to talk about the scope of VCCEP. I was confused about the scope - about what would be included - prior to coming to the meeting, and I am more confused now. We have talked about degradates. Are they in play? Some of these chemicals are factors in ozone formation. There are innumerable possibilities as to what some of the potential impacts are for, however small, for some of these chemicals. I would like to ask EPA if there will be some further consideration and guidance as to what you would like us to consider now or at a later date?

EPA Comment: We need to be extremely sensitive to the terms of the program involving the peer consultation process. To indirectly address your question, some people were talking last night about getting together with the sponsors and maybe talk about more examples or develop more test cases, and maybe see what we can do so that people do not have to reinvent the wheel or duplicate effort. The advantage of doing something like that is it promotes efficiency, collegiality, sharing of information. The disadvantage is that it may ultimately inadvertently preempt the peer consultation process by making a subliminal suggestion that EPA is giving an imprimatur to a particular study, a particular approach, or a particular group. And so, I think that we will continue to refine our thinking on how we will be using and approaching information but we do need to be very careful to make sure that is not misinterpreted as what the peer consultation panel will find adequate, overkill, underkill. And so we are kind of walking a fine line. I think we will certainly go back and look at the examples that we have presented here and see if we can make them more useful not only for us but also for other people. Many, many of the comments that have been raised here are very helpful in doing that. But it is a little bit

delicate for us to be providing guidance for a voluntary program; on the other hand it is not fair to not tell you what we think is important because we are among the customers for the data. So we are walking that tightrope right now.

Panelist Comment: As I have been listening to this discussion I am struck by, the way I want to categorize in my own mind anyway, the types of information that will be generated and the audience to whom we need to communicate that information. The way I am breaking it down in my own mind is there is going to be the technical document, the big submittal, that says what has been done, in detail, why the decisions have been made, etcetera. And that is going to the peer consultation. That will have some flexibility and variability depending on what the chemical is and the approach taken to it. Then we talked about what was presented with these summaries, and I look at those summaries, and those summaries will be tailored to whatever is in that technical document. And these robust summaries go along with the technical document, and they are giving you the road map to whatever you are reading in the technical document.

There is another level that is the first cut that the public will see that we have to extract information from the technical document and robust summaries in a format that is more readily informative in communicating to the public. The example I think of, whether you liked it or not, was when ATSDR did all of those toxicological profiles, you could go on line, and there was a two to three page fact sheet. You did not have to go to their technical document, but you had another cut above that. It seems from the discussions and concerns that this may be a way for framing the kinds of documents and information and a possible format in which to produce them.

Panelist Comment: I want to emphasize that I think there is a need for innovation and creativity in the context of a pilot process. There needs to be some creativity allowed, and I think there will be opportunity for that.

I also wanted to comment on the upside down pyramid method of focusing assessments. Quite frankly, it is the only practical way to go forward with this. I do think, from the perspective of a peer consultation process, that the step 2 that Elizabeth Anderson articulated might need some additional information and additional rationalization. And that probably would happen as part of the presentation to the peer consultation consultants.

I would also suggest that the single point estimates that are provided in any document. need to have some sort of additional context. What kind of statistical metric are you representing? Too often, even though we call something an “average dose” it really ends up being an upper percentile average, or something else. There is just too much mystery there. That can be misleading and lead to a lot of misinformation. In the same way, you need to be pretty explicit about the scenario that you are representing. Are you assuming that people live in a carpeted home for their entire life? Are they going to be exposed every day for

their entire life? That needs to come out very explicitly. Otherwise it gets buried in the details, and that gives the average person a very quick and intuitive understanding of what you are doing.

Panelist Comment: I wanted to come back to one of the questions, which tasked the question, "Are these the right kinds of elements to be addressing?" From the standpoint of the elements that are described in EPA's summaries, for the most part, I think those make sense. We did hear some concerns today about facilities that will want to bring their blueprints and there may be some CBI concerns in some cases that really cannot be overcome through innovative approaches. Those we may need to deal with. I was thinking that in today's environment since September 11, security is a new dimension of concern, and I am sure there will be some sponsors that will have to consider security kinds of questions.

I do think the top line elements make sense. There are other kinds of examples that were mentioned: the work that has been going on at OECD that has identified some things, the Alliance for Chemical Awareness has their suggested elements which are very comparable to these (http://www.chemicalawareness.org/), and the ACC prospective paper there is a similar outline with the same elements but with more of a free text sort of approach. At the issue of elements to be addressed, I think we are on the same footing. And I think we have talked today about what is the flexibility around how we address those to really provide the relevant information that needs to be addressed. And, let's dot the i's in a thorough way that need to be dotted and not worry about those that do not.

In terms of the summaries, the summaries that are being described (e.g. Summary of Modeling Evaluations or the Summary of Monitoring Evaluations) I think of them more as references. Rather than just a one-line reference, "See paper submitted to Environmental Health Perspectives," it really is an attempt to actually detail the reference in a more uniform manner, as opposed to a higher level perspective on what the assessment means. It is a reference to allow the reader in a transparent way to be clearer about where this number comes from.

Panelist Comment: I agree with that point and I think that may be very useful because we are talking about data quality and where is that coming from. I was thinking more that people did not want the detail in here, and tables, and hearing some concern that people were not going to be able to fill out tables. I think that some sort of summary to say what we have considered and to provide an overview would be helpful. But this robust summary differs in the sense that it goes beyond other sorts of executive summaries in doing the monitoring. I think that is an additional factor, but it is a useful one if sponsors feel it is appropriate to put it in there for their major monitoring efforts.

3.0 PART III: PEER CONSULTATION, HAZARD AND RISK ASSESSMENT, AND DATA NEEDS

Part III of the workshop included presentations by Jacqueline Patterson from Toxicology Excellence for Risk Assessment (TERA) and Jennifer Seed, Chief of EPA's Existing Chemicals Assessment Branch.

3.1 Overview of Toxicology Excellence for Risk Assessment (TERA)

Jacqueline Patterson

Ms. Patterson presented an overview of TERA's peer review process and how that process might be applied to the VCCEP program. She noted that the details of the VCCEP peer consultation process have not been finalized; the information she presented was based on experiences with similar programs.

Ms. Patterson presented TERA's mission and purpose statement, which is to protect public health through risk communication and research. TERA is involved in a variety of programs involving risk assessment and peer review, and will use existing peer consultation models for the VCCEP program. Ms. Patterson described TERA's typical algorithm for conducting the peer consultations.

During the first quarter of 2002, TERA expects to solicit nominations for experts for their consultation panel, select members, and conduct a workshop to explain their process. During the second quarter of 2002, TERA expects to hold the first VCCEP panel consultation meeting. It is expected that TERA will host one panel consultation per quarter. Panel members will be continuously identified for specific chemicals that are due for peer consultation.

Slides for Ms. Patterson's presentation are available on the EPA Chemical Right-To-Know website at http://www.epa.gov/chemrtk/expagnda.htm by clicking on the title of the presentation in the agenda.

Clarifying questions

Panelist Question: What is the estimated size of the core peer consultation group?

Presenter Response: An ideal size for a peer consultation group is typically 8 to 12 people. The exact numbers of permanent core panel members and invited ad hoc members of the panel will likely vary and has not yet been determined.

Panelist Question: Has TERA has discussed the anticipated duration of the peer consultation meetings and the time required for the panel participants to prepare for the meetings?

Presenter Response: TERA has not yet determined these time requirements; however, similar efforts have required 2 days of peer meetings per consultation. This requirement may vary by chemical. The estimated preparation time for the panel members will depend significantly upon the chemical, and perhaps one month of preparation time would be appropriate to review the relevant information. It is likely that TERA will request pre-meeting comments, which will help to focus the meeting discussions.

Audience Question: Will information be available to the public prior to the peer consultation review, will the peer consultation meetings be open to the public, and what sort of information will be released after the meetings?

Presenter Response: Ms. Patterson responded that TERA is currently working through the details of these issues; however, the meetings will be open to the public, there will be some opportunity for public attendance and comment, and the results of the meetings will be summarized and published on the TERA website.

Panelist Question: The time line Ms. Patterson presented indicated there will be one panel meeting per quarter for each chemical. Is this the same schedule as published in the VCCEP Federal Register notice?

EPA Response: The schedule is the same as that published in the Federal Register notice; however, reality may dictate a different schedule.

Presenter Response: The schedule was set based on the total number of chemicals and the total program length of five years. The actual schedule will be based upon the readiness of the sponsors.

Panelist Question: Some peer consultation programs require significant amounts of time (e.g., the phthalate esters program). If the panel has difficulty coming to an agreement or finishing their work in the time frame allotted, will there be an option to end the panel or to continue it at a later date?

EPA Response: This is not a consensus process, and therefore, there is no driver to extend the sessions in order to reach consensus. If the peer consultation group is able to define the issues well, then that could be considered a satisfactory outcome.

Panelist Question: Is TERA is considering conducting any of these meetings via teleconference? I suggest that preliminary questions or comments for the sponsor could be conducted via teleconference to allow the sponsor time to assemble that information prior to the panel convening.

Presenter Response: In the past, TERA has also found sharing preliminary comments with the sponsors facilitates the process. Additionally, if it becomes necessary to reconvene the panel for some reason, teleconferences are useful.

Panelist Question: The flow chart depicting the peer consultation process indicates that TERA will conduct a preliminary review of the Tier 1 data packages. Will this preliminary review indicate whether the Tier 1 assessment could be refined further without entering into a Tier 2 assessment, based on comment from TERA?

Presenter Response: TERA's initial review will be a brief quality control review, simply to ensure that the package is complete; a detailed review will not occur prior to convening the peer consultation panel. It is possible that the consultation panel might make recommendations to the sponsor, including data sets that could be used to refine the assessment; however, I am not sure whether that will be considered Tier 1 or Tier 2.

Panelist Question: How will the members of the peer consultation panel be selected, considering that there are acknowledged experts for some of these chemicals?

Presenter Response: Each chemical assessment will be reviewed when it is received, and the appropriate people will be identified based on that review. TERA will contact the known panelists to solicit their involvement, and the sponsors are encouraged to invite to the peer consultation meetings experts who may be helpful in explaining their approach.

3.2 EPA's Perspectives of Hazard Assessment, Risk Assessment, and Data Needs

Jennifer Seed, EPA Existing Chemicals Assessment Branch

Dr. Seed presented EPA's outlook on using hazard, dose-response, and exposure information to compile a risk assessment. Dr. Seed began her presentation by reviewing the Risk Assessment Paradigm. First, the problem is formulated by asking the question, "Have the risks to children been adequately characterized?" The hazard assessment and the exposure assessment may then be compiled based on the response to this question. The data from these assessments are used to create the risk assessment. After the risk assessment completes the peer consultation process, the results are reviewed to identify if the problem question was answered sufficiently. These steps reflect an iterative process, and are revisited as needed.

EPA's Risk Assessment Forum has initiated several activities to develop information on children's exposure. The forum produced a draft document outlining recommendations resulting from these activities, including a formal assessment of available EPA test guidelines. These data are presented in diagrams which show the life stage of the animal and the affected organ or system. These diagrams may be useful for the sponsor in determining where data are available appropriate to their assessments.

Dr. Seed closed her presentation by reviewing some of the relevant resources in conducting a risk assessment, including the EPA Risk Characterization Handbook and the principles of transparency, clarity, consistency, and reasonableness.

Slides for Dr. Seed's presentation are available on the EPA Chemical Right-To-Know website at http://www.epa.gov/chemrtk/expagnda.htm by clicking on the title of the presentation in the agenda.

Clarifying questions:

Panelist Question: I am disappointed that epidemiological and clinical studies have been completely absent from these presentations and the subsequent discussions. These studies integrate the hazard and exposure information already in the relevant species and at levels one would expect to see in the environment, reducing the need to use default values and assumptions. The VCCEP framework should list and emphasize using epidemiological studies data.

Presenter Response: These data were not left out intentionally. Epidemiological and clinical data are appropriate to use and their use should be encouraged.

Audience Question: The slides containing charts on the life stages in standard toxicity testing protocols should have indicated a logarithmic scale. The scale used de-emphasizes the importance of the subchronic and chronic studies, which covers 104 weeks of exposure. In addition, these studies are typically conducted at maximum tolerated doses that produce some marginal degree of toxicity, or even a high degree of toxicity. This dose does not reduce the size of the exposure group to a point that compromises the study. That information is particularly important relevant to reproductive organs and other toxicities that one would be concerned about with respect to children.

Presenter Response: These charts had no scale, and were designed to include all of the desired information. The purpose of presenting these charts is to encourage the use of all data that is available from the epidemiological and animal studies across life stages.

3.3 General Discussion IX

The meeting facilitator opened the discussion to panel members and audience members.

A panelist commented that odors, tastes, and other organoleptic issues are important to children's health, and there is a lack of data related to these issues in this presentation.

A panelist expressed concern that the teleconferences prior to the peer consultation meetings would not be open to the public, and suggested that this be considered. Ms. Patterson clarified that all meetings convening the panel will be open to the public.

An audience participant noted that various stakeholder groups will be allowed to nominate panel members for the peer consultation process. To avoid creating a potential or perceived conflict of interest, the nominations should be submitted to an independent third party so that the panel members will not know who nominated them.

A panelist suggested that TERA consider inviting pediatricians to serve on the peer consultation panel.

No additional comments or topics for discussion were presented.

4.0 CLOSING REMARKS

Closing remarks were provided by A. Michael Kaplan, Director - Regulatory Affairs of the DuPont Haskell Laboratory; George Lucier, consultant to Environmental Defense; and Mary Ellen Weber, Director of EPA's Economics, Exposure, and Technology Division.

4.1 ACC Closing Remarks

A. Michael Kaplan, Ph.D. DuPont Haskell Laboratory

Dr. Kaplan began his remarks by thanking the presenters, panelists, EPA, and the audience for their commitment of time, cooperation, and their comments during this workshop.

Dr. Kaplan summarized some key points of the workshop. There is more than one way to approach a children's exposure assessment, and many tools and models are available for use in conducting an assessment. ACC presented their view on a tiered approach to exposure assessment, including the discussion of one possible framework. Sciences International developed and presented another case study. EPA presented their view on the nested approach to summarizing exposure information. Throughout the presentations, the principles of quality, completeness, and transparency have been repeated.

Dr. Kaplan reiterated that VCCEP necessitates flexibility, and the pilot nature of this program should give sponsors the ability to take advantage of the approaches they feel are best suited for their situation. The workshop marks the completion of another step in the process of increasing knowledge about evaluating the potential risk of chemicals to children.

Dr. Kaplan urged the sponsors to thoroughly collect, evaluate, and integrate their information, and urged EPA to continue to work closely with industry to ensure that VCCEP remains a cooperative venture. In 1999, EPA and industry agreed to try and develop an alternative to chemical test rules that would tier and integrate hazard and exposure information. VCCEP is the result of that agreement, and it requires the best efforts of everyone involved.

Dr. Kaplan quoted Steve Johnson from the first day of the conference, "EPA is in a partnership with industry," and noted that industry is committed to making this program a success. Dr. Kaplan encouraged the sponsors to take the opportunity to use innovative approaches. This is a pilot program, and "we will learn by doing…Through this partnership, let's get some results."

4.2 Closing Remarks

George Lucier, Ph.D., Consultant to Environmental Defense

Dr. Lucier thanked the participants for their candor, patience and objectivity. He thanked the ACC for their commitment to make the program work, and the EPA presenters for their time and efforts. He also thanked the participating public interest groups, including Environmental Defense, Physician's Committee for Responsible Medicine, Children's Environmental Health Network, National Resources Defense Council, and all of the other participating organizations. He believes everyone is in support of the common goal to make the VCCEP program work.

Dr. Lucier noted comments regarding the challenges ahead for VCCEP, including:

$ What constitutes each of the tiers, and how much information should be included in Tier 1? For now, it may be prudent to include too much information rather than too little. It is important that assessments of the first pilot chemicals are successful.

$ Will there be flexibility to skip tiers based on good justification? Probably not, but there is currently no conclusive position on that issue.

$ Sponsors should seek exposure information from other agencies early on, particularly the USDA, FDA, and the CDC.

$ Exposure assessment needs to be placed in the context of the hazard data without compromising the completeness of the assessment.

$ Sponsors are encouraged to be innovative in developing exposure and hazard data. This should include the use of scientifically sound and relevant methods that address animal welfare issues.

$ Can a flexible framework be developed to accommodate the very wide exposure circumstances represented by VCCEP chemicals, and at the same time, foster consistency and good comparisons across various chemicals?

$ Can exposure models be integrated with real biomonitoring data? Biomonitoring provides a good integrated endpoint for use in exposure assessments, and avoids the complexities of developing models.

$ There needs to be some agreement that there will be some circumstances where biomonitoring data show that exposure is occurring, but is slow enough so that children are not at risk.

$ There needs to be some agreement that industry can embark on exposure reduction programs, not because they have done anything wrong, but rather because it is the right thing to do.

$ It is important to generate common language summaries acceptable to all stakeholders. This will go a long way in building public confidence as we move through the peer consultation process.

Dr. Lucier closed his remarks by stating that good progress has been made, and he believes there is enough good will and motivation for this program to make it successful.

4.3 Workshop Closure and Next Steps

Mary Ellen Weber, Ph.D. EPA

Dr. Weber thanked the VCCEP sponsors, ACC, the audience, the panelists, and EPA's consultants for their participation and contributions to this workshop. Compromises have been made throughout the development of this program, and they will continue to be made during the course of this endeavor. As a result, nobody is going to get everything they want out of the program, but EPA hopes that the process of working together will be advantageous to everyone.

Referring to the ACC flow chart developed for the VCCEP pilot, Dr. Weber noted that the VCCEP process will sometimes lead to voluntary discussions between the various stakeholders, industry, and EPA, where ideas may be exchanged. The process is intended to be flexible, which is not to imply incompleteness, but rather, innovation and clarity. The program is intended to inform choices and allow the interested parties to work together in developing risk communication and risk reduction.

Dr. Weber reiterated a comment by George Lucier, "Voluntary steps to reduce exposures doesn't necessarily mean that anyone has done anything wrong or failed to do the right thing." EPA believes that VCCEP sponsors are participating in the spirit of pollution prevention, source reduction, and observing opportunities to operate efficiently.

Dr. Weber noted items that need further attention after this workshop:

$ It is critical to determine how risk will be communicated.

$ Sponsors should contact other government agencies that may have exposure information for their chemical. EPA may be able to facilitate that process.

$ The development of an exposure assessment is an iterative process. The exposure information will complement and provide a context for the hazard data.

- $ EPA's Summary Formats were not intended to be used independently of the frameworks presented during the workshop. EPA intended that the Formats could be used as the robust summary requested in the VCCEP Federal Register notice.

Dr. Weber closed the workshop noting that EPA is available to participate in any follow-up discussions, without preempting or prejudging the adequacy of any particular approach. Workshop materials will be made available on the EPA web site.

APPENDIX 1

United States
Environmental Protection Agency
Office of Pollution Prevention and Toxics

Co-sponsored by
American Chemistry Council

EPA/ACC Technical Workshop for the Voluntary Children=s Chemical Evaluation Program (VCCEP)

Hyatt Dulles Airport Hotel
Herndon, Virginia
December 11-13, 2001

Agenda

TUESDAY, DECEMBER 11, 2001

8:00AM Registration/Check-In

PART I: BACKGROUND

Moderator: Mary Ellen Weber, Ph.D.

9:00AM Welcome and Introduction ..... *Steve Johnson*
Assistant Administrator
Office of Prevention, Pesticides and Toxic Substances (OPPTS)
U.S. Environmental Protection Agency (U.S. EPA)

9:20AM Purpose of Workshop ..... *Mary Ellen Weber, Ph.D.*
Director
Economics, Exposure, and Technology Division (EETD), U.S. EPA

9:30AM Orientation to VCCEP ..... *Ward Penberthy*
Associate Director
Chemical Control Division (CCD), U.S. EPA

9:50AM Industry Participation in VCCEP ..... *Bill Greggs*
Regulatory Affairs Manager
The Procter & Gamble Company

10:00AM Importance of Sound Science in VCCEP ..... *George Lucier, Ph.D.*
Consultant to Environmental Defense
Science Advisory Board, U.S. EPA

TUESDAY, DECEMBER 11, 2001 (continued)

PART II: EXPOSURE

Moderator: Jan Connery, ERG, Inc.

10:10AM Introduction of Panel and Discussion Format
Jan Connery, Facilitator

A. OVERVIEW OF EXPOSURE ASSESSMENTS

10:25AM Overview of Exposure Assessment ..... *Cathy Fehrenbacher*
Chief, Exposure Assessment Branch (EAB)
EETD, U.S. EPA

Presentation - 15 minutes
Clarifying questions from panel and audience - 20 minutes

11:00AM BREAK

11:10AM Children's Exposure Assessment ..... *Elaine Cohen Hubal, Ph.D.*
Chemical Engineer
National Exposure Research Laboratory, U.S. EPA

Presentation - 25 minutes
Roundtable Discussion (Panel members) - 25 minutes
Open Discussion - 25 minutes

12:25PM BOXED LUNCH PROVIDED

1:25PM Perspectives on Tiered Exposure Assessments
for VCCEP ..... *Richard A. Becker, Ph.D.*
Senior Director
American Chemistry Council (ACC)

Presentation - 20 minutes
Roundtable Discussion (Panel members) - 20 minutes
Open Discussion - 20 minutes

2:25PM A Tiered Approach for Assessing
Children's Exposures ..... *Rosemary Zaleski*
Senior Environmental Scientist
Occupational and Public Health Division,
ExxonMobil Biomedical Sciences, Inc.

Presentation - 20 minutes
Roundtable Discussion (Panel members) - 30 minutes
Open Discussion - 30 minutes

3:45PM BREAK

TUESDAY, DECEMBER 11, 2001 (continued)

B. RESOURCES AND MODELS

4:00PM References and Resources for Exposure Assessments ..... *Patrick Kennedy*
Senior Chemist, EAB
EETD, U.S. EPA

Presentation - 20 minutes

4:20PM The Child Specific Exposure Factors Handbook ..... *Jacqueline Moya*
Environmental Engineer
National Center for Environmental Assessment, U.S. EPA

Presentation - 30 minutes
Roundtable Discussion (Panel Members) - 20 minutes
Open Discussion - 30 minutes

5:40PM ADJOURN

WEDNESDAY, DECEMBER 12, 2001

8:30AM RECAP: Summarize Key Information From Previous Day to Lead Into Discussions on Days Two and Three

9:00AM Relevant Models for Exposure Assessments of VCCEP Chemicals ..... *Paul S. Price, M.S.*
Director
The Lifeline Group

Presentation - 30 minutes
Roundtable Discussion (Panel members) - 25 minutes
Open Discussion - 25 minutes

10:20AM BREAK

C. EXAMPLE EXPOSURE ASSESSMENTS (IN PLENARY SESSION)

10:40AM Overview of Basic Principles: Transparency, Completeness, Data Quality, and Consistency ..... *Patrick Kennedy*
Senior Chemist, EAB
EETD, U.S. EPA

Presentation - 20 minutes
Clarifying questions from panel and audience - 30 minutes

WEDNESDAY, DECEMBER 12, 2001 (continued)

11:30AM BOXED LUNCH PROVIDED

12:40PM Example (Part 1): Integrated Exposure Assessment Relevant to Children=s Exposures .....*Fred Arnold*
Chemical Engineer, Chemical Engineering Branch (CEB)
EETD, U.S. EPA

Presentation - 30 minutes
Roundtable Discussion (Panel members) - 20 minutes
Open Discussion - 30 minutes

2:00PM Example (Part 2): Integrated Exposure Assessment Example Relevant to Children=s Exposures .....*Gary Bangs*
Environmental Health Specialist, EAB
EETD, U.S. EPA

Presentation - 30 minutes

2:30PM BREAK

2:45PM Example (Part 2) con=t...

Roundtable Discussion (Panel members) - 20 minutes
Open Discussion - 30 minutes

3:35PM Framework for Integrating Exposure Information .....*Elizabeth L. Anderson, Ph.D.*
President & CEO
Sciences International, Inc.

Presentation - 25 minutes
Roundtable Discussion (Panel members) - 25 minutes
Open Discussion - 30 minutes

4:55PM Audience Q & A

5:30PM ADJOURN

THURSDAY, DECEMBER 13, 2001

8:30AM RECAP: Summarize Key Information From Previous Day to Lead Into Discussions on Day Three

D. EPA=S DRAFT EXPOSURE SUMMARIES

*9:*00AM Draft Exposure Summaries.....*Nhan Nguyen*
Chief, CEB
EETD, U.S. EPA

Presentation - 20 minutes
Clarifying questions from panel and audience - 20 minutes

9:40AM Example Format (for an Integrated Exposure Assessment Relevant to Children=s Exposures) .....*Jennifer S. Faraci*
Industrial Hygienist, CEB
EETD, U.S. EPA

Presentation - 25 minutes
Roundtable Discussion (Panel members) - 30 minutes
Open Discussion - 25 minutes

11:00AM BREAK

PART III: PEER CONSULTATION, HAZARD AND RISK ASSESSMENT, AND DATA NEEDS

11:15AM Overview of Toxicology Excellence for Risk Assessment (TERA) ..... *Michael Dourson, Ph.D.*
Director
Toxicology Excellence for Risk Assessment

Presentation - 15 minutes

11:30AM EPA=s Perspectives on Hazard Assessment, Risk Assessment, and Data Needs .....*Jennifer Seed, Ph.D.*
Chief, Existing Chemicals Assessment Branch
Risk Assessment Division, U.S. EPA

Presentation - 30 minutes
Open Discussion - 30 minutes

12:30PM ACC Closing Remarks.....*A. Michael Kaplan, Ph.D.*
Director B Regulatory Affairs
DuPont Haskell Laboratory

THURSDAY, DECEMBER 13, 2001 (continued)

12:45PM Closing Remarks ..... *George Lucier, Ph.D.*
Consultant to Environmental Defense
Science Advisory Board, U.S. EPA

1:00PM Workshop Closure and Next Steps ..... *Mary Ellen Weber, Ph.D.*
EETD, U.S. EPA

1:15PM ADJOURN

APPENDIX 2

United States
Environmental Protection Agency
Office of Pollution Prevention and Toxics

Co-sponsored by
American Chemistry Council

EPA/ACC Technical Workshop for the Voluntary Children=s Chemical Evaluation Program (VCCEP)

Hyatt Dulles Airport Hotel
Herndon, Virginia
December 11-13, 2001

Invited Technical Expert Biographies

Henry Anderson

Biography not available.

Glen Barrett

Glen Barrett received his B.S. in chemistry and M.S. in inorganic chemistry from Marquette University. He is a Certified Industrial Hygienist in the comprehensive practice of industrial hygiene. Mr. Barrett has more than 25 years of experience in all aspects of health, environmental, and safety issues, including human health and ecological risk assessments, exposure assessment surveys and design for all types of industry, industrial hygiene program management, health and safety program management and training, and control technology assessment.

Mr. Barrett is employed by the American Petroleum Institute as a Senior Health Scientist. He staffs the TSCA Task Force and monitors all TSCA issues, including the VCCEP and the HPV Challenge. He is involved with risk assessment, as well as investigates public health from exposure to gasoline oxygenates, criteria pollutants, and other chemicals. Mr. Barrett is a member of the American Industrial Hygiene Association (AIHA) and its Risk Assessment Technical Committee. He chaired the last two AIHA risk assessment symposiums and is currently chairing the organization of the 2002 risk assessment symposium.

Barbara F. Bass

Barbara Bass has a B.A. in psychology and a B.S. in biology from Trinity College, and a Ph.D. in toxicology from Johns Hopkins University. With approximately 30 years of experience in the environmental arena, she has worked primarily as an environmental consultant focusing on scientific, regulatory, and policy issues in areas including risk assessment, environmental reporting required of industry and states, environmental benefits of EPA programs, the use of toxic chemicals and their release into the environment, and pollution prevention.

Dr. Bass is currently an independent consultant working on projects for government agencies, foundations, and non-profit organizations. Recent activities have ranged from the evaluation of specific issues associated with implementation of the Title V program under the Clean Air Act to researching the flow of environmental enforcement and compliance data that the States are required to report to EPA and the sources of inconsistencies in these data. Dr. Bass has recently completed a 3-year term as Councilor on the National Capital Area Chapter of the Society of Toxicology.

Nicole Cardello

Nicole Cardello, M.H.S., is the staff scientist with the Physicians Committee for Responsible Medicine (PCRM), a nationwide organization of physicians that promotes preventive medicine and addresses controversies in modern medicine, including ethical issues in research.

Ms. Cardello earned a Bachelor of Science in Public Health degree in the field of Environmental Science from the University of North Carolina at Chapel Hill and a Master of Health Science in Environmental Health Engineering degree from Johns Hopkins University. Ms. Cardello has held environmental science research posts in academia and with the EPA, where she investigated the effects of environmental and occupational chemical exposures on public health.

Ms. Cardello is a member of the International Society of Exposure Analysis and has presented at American Industrial Hygiene Association conferences. Her paper entitled "Performance of a Personal Electrostatic Precipitator Particle Sample" has been accepted for publication in Aerosol Science and Technology.

James Cooper

Biography not available.

Jeffrey Driver

Biography not available.

Bill Greggs

Bill Greggs is a Technical External Relations Manager in Procter & Gamble's Product Safety and Regulatory Affairs Division. Bill joined P&G after receiving his Bachelor of Science in Chemical Engineering from Lafayette College in Easton, Pennsylvania in 1971. He worked for 20 years in manufacturing management positions in a number of P&G's Paper product plants. Since 1990, Bill has worked on a number of legislative, regulatory and technical policy issues affecting the Company and it's products, including recycling, consumer labeling, antimicrobial product registration and chemical information sharing. Currently his focus is on chemicals management issues. He has global responsibility for P&G's involvement in HPV and Children's Health programs. For the US and ICCA HPV programs, he is involved in the development of assessments in 10 industry consortia.

Bill is a member of the American Chemistry Council Children's Health and Product

Stewardship Teams. He was involved in development of the Council's proposals for assessment of chemicals in the VCCEP program and served on the VCCEP stakeholder panel. He is also active on the Alliance for Chemical Awareness Communications committee, which has developed a framework for presenting the results of screening level chemical assessments.

George Lucier

George Lucier is currently an adjunct toxicologist for Environmental Defense, a consultant and advisor to NIEHS, Chair of the Science Advisory Board for the Regulation of Hazardous Air Pollutants for the state of North Carolina. He is a member of the SAB for EPA on the committee for Integrated Exposure Assessment and several other boards and committees dealing with environmental health issues. Dr. Lucier retired as Director of the Environmental Toxicology Program of the NIEHS and as Associate Director of the NTP. He also retired from being editor of the Journal Environmental Health Perspectives, a post held for 28 years. He published nearly 300 scientific articles, most dealing with environmental health and risk assessment.

Jacqueline Moya

Ms. Jacqueline Moya has 17 years of experience as a chemical engineer with the EPA. In 1987, Ms. Moya joined NCEA Washington (formerly the Exposure Assessment Group) where she directs research projects to develop or enhance exposure assessment methodologies and directs, conducts, and reviews exposure and risk assessments at hazardous waste sites. Ms. Moya is an expert in the area of exposure assessments and specifically on issues regarding exposure factors research, the appropriate use of exposure factors data and exposure scenarios. Ms. Moya was the project manager and contributing author in charge of the production of the U.S. EPA Exposure Factors Handbook in 1997. Since its publication, Ms. Moya has created a comprehensive program to direct research to fill data gaps found during the production of the Handbook. More recently, Ms. Moya has been in charge of producing the Child-Specific Exposure Factors Handbook as well as being a contributing author.

Paul Scott Price

Mr. Price has a Masters degree in Civil Engineering (University of Maryland, 1979) and a Bachelors degree in Chemistry (University of Maryland, 1974). Mr. Price has more than 20 years of experience in assessing exposure to chemicals for industry, government, and trade associations.

Mr. Price is a Director of The LifeLine Group, which develops software for the assessment of exposure to pesticides and other substances. He has authored over 20 articles on exposure and risk assessment and served on numerous Task Forces and External Peer Reviews for EPA, DOD, and California. Areas of interest include dose reconstruction, aggregate and cumulative risk, integration of toxicity and exposure data

using simulation models, pesticide exposure, and exposures related to the consumption of fish.

Dennis Paustenbach
Biography not available.

Bill Weil
Biography not available.

Rosemary Zaleski

Rosemary Zaleski has a B.A. in Biochemistry from Cook College and an M.S. in Environmental Sciences from Rutgers University. She has 12 years of experience in environmental fate and effects and exposure assessment. Her experience includes multimedia and exposure modeling. Ms. Zaleski is currently employed by ExxonMobil Biomedical Sciences, Inc., in the Exposure Sciences and Human Factors Section of the Occupational and Public Health Division. She recently completed a probabilistic children's exposure assessment for the European Chemical Industry Council. She is a member of the Alliance for Chemical Awareness (ACA) technical committee, where she co-led development of an ecological exposure and risk framework and contributed to the development of human exposure frameworks. She is/has been involved in a number of American Chemistry Council exposure initiatives, including the VCCEP exposure subteam, a summary of children's exposure factors information, the review team for the USEPA Child Specific Exposure Factors Handbook, and the Exposure Action Team.

APPENDIX 3

United States
Environmental Protection Agency
Office of Pollution Prevention and Toxics

Co-sponsored by
American Chemistry Council

EPA/ACC Technical Workshop for the Voluntary Children=s Chemical Evaluation Program (VCCEP)

Hyatt Dulles Airport Hotel
Herndon, Virginia
December 11-13, 2001

Presenter Biographies

Elizabeth L. Anderson, Ph.D., Sciences International, Inc.

Dr. Elizabeth Anderson, ATS Fellow, has a Ph.D. in organic chemistry from The American University, a M.S. in organic chemistry from the University of Virginia, and a B.S. in chemistry from the College of William and Mary. She has been President and C.E.O. of Sciences International Inc. for the past 8 years. Prior to that, she was President, C.E.O., and Chairman of the Board of Clement International Corporation. At the USEPA, she established and directed the central risk assessment program for 10 years. Specifically, in 1976, Dr. Anderson established the Carcinogen Assessment Group (CAG) which formed the core for the later Office of Health and Environmental Assessment, which she also directed. Dr. Anderson is an internationally recognized lecturer and consultant and has published numerous journal articles in the areas of health and environmental risk assessment. She is the recipient of the EPA Gold Medal for Exceptional Service.

Dr. Anderson's current work focuses on multimedia exposure assessment and consequent cumulative risk. She has served on numerous committees and panels, including serving as a member of the NRC Committee on Assessment of Risks from Remediation of PCB-Contaminated Sediments, the External Evaluation Group for the Los Alamos National Laboratory, the USDA Peer Review Panel for the Office of Risk Assessment and Cost Benefit Analysis, and the Peer Review Committee for the Assessment and Recommendations for the South Carolina Air Toxics Standard. She is also currently Editor-in-Chief of *Risk Analysis: An International Journal.*

Fredric C. Arnold, Ph.D., J.D., U.S. Environmental Protection Agency

Dr. Arnold is an engineer in the Chemical Engineering Branch of the Office of Pollution Prevention and Toxics of EPA. He has been with EPA since 1994. He received his doctorate in Chemical Engineering from the University of Minnesota and recently completed his Juris Doctorate degree at George Mason University. He is the author of publications in engineering and mathematical simulation including contributions to the text, Green Engineering - Environmentally Conscious Design of Chemical Processes sponsored by the Chemical Engineering Branch. Dr. Arnold is a licensed professional engineer and a member of the Virginia State Bar.

Gary W. Bangs, U.S. Environmental Protection Agency

Gary Bangs works with the Exposure Assessment Branch of the Office of Pollution Prevention and Toxics in the areas of exposure and risk assessment. Mr. Bangs also works with the Office of Pesticide Programs as an exposure and risk assessor. He has performed many occupational and residential exposure and risk assessments for pesticides. Mr. Bangs is a Commissioned Officer of the US Public Health Service, and has been on detail to the US EPA since 1998. His previous experience includes over 10 years in occupational health settings: establishing and

evaluating safety and health programs, developing worker safety training, and performing field investigations. Field experience includes exposure studies of worker exposures to asbestos, lead, solvents, and physical agents (such as noise and heat). Mr. Bangs has performed numerous indoor environmental quality studies. He has presented papers at local and national professional conferences. He received a B.A. in Biology from the University of Pennsylvania in 1977, a B.S.N. in Nursing from the University of Miami in 1980, and an M.P.H. from the University of Washington in 1992. He is currently certified in Comprehensive Practice of Industrial Hygiene, and is a Registered Nurse.

Richard A. Becker, Ph.D., American Chemistry Council

Richard A. Becker earned a B.A. in Chemistry from Swarthmore College and a Ph.D. in Pharmacology and Toxicology from the University of California, and received post-doctoral training at the University of Toronto and the International Agency for Research on Cancer. His training in toxicology and risk assessment includes reproductive and developmental toxicology and chemical carcinogenesis, and he is a Diplomate of the American Board of Toxicology. He has served as study director for NTP and NCI sponsored toxicity studies, and was a senior scientist with the State of California for more than 10 years. His experience in government service includes serving as both Deputy Director of Scientific Affairs and Director of the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment and as the Senior Toxicologist in the Department of Toxic Substances Control. In these positions, he focused on development of hazard evaluations, exposure assessments and risk characterizations to determine health and environmental threats posed by the release of hazardous substances into the environment.

Dr. Becker is currently the Senior Director of the Public Health Team of the American Chemistry Council. He works as the organization’s lead toxicologist in addressing emerging health risk science issues, including hormonally active agents, sensitive subpopulations, and new and alternative test methods.

Elaine Cohen Hubal, Ph.D., National Exposure Research Laboratory, U.S. Environmental Protection Agency

Biography not available.

Jennifer Faraci, CIH, U.S. Environmental Protection Agency

Jennifer Faraci is an Industrial Hygienist with the Chemical Engineering Branch in the Economics, Exposure, and Technology Division, Office of Pollution Prevention and Toxics. Jennifer joined the branch in 2000. She is a Certified Industrial Hygienist (CIH), and prior to joining the EPA, she worked in both industry and government consulting. Her areas of expertise include occupational exposure assessment and sampling, ventilation, and personal protective equipment. Since joining EPA, she has contributed significantly to respiratory

protection policies and selection procedures for the office and also to the New Chemical Exposure Limit (NCEL) program. Jennifer received a B.A. from the College of William and Mary in International Studies in 1992 and an M.P.H. from the University of California at Berkeley in Environmental Health Science in 1996.

M. Cathy Fehrenbacher, M.S., CIH, U.S. Environmental Protection Agency

Ms. Fehrenbacher is the Chief of the Exposure Assessment Branch in the Office of Pollution Prevention and Toxics at the U. S. Environmental Protection Agency in Washington, D.C. She is a Certified Industrial Hygienist and has over 15 years of experience in various aspects of industrial hygiene and exposure assessment. In her current position, Ms. Fehrenbacher manages an interdisciplinary group of scientists and engineers responsible for assessing exposure of consumers, the general public, communities, and the environment to chemicals and biological agents, and assessment of environmental fate and transport. The Exposure Assessment Branch is responsible for developing and using exposure assessment methods (including many predictive models and databases), providing technical support to OPPT's regulatory and voluntary programs, and working with other scientists and researchers in the U.S. and abroad on harmonizing exposure assessment methods, enhancing the science of exposure assessment, and sharing information. She has authored or co-authored several publications and chapters on the use of modeling approaches for predicting inhalation and dermal exposure, and has given numerous presentations and lectures on EPA's programs, methods, and policies for assessing and managing chemical risks.

William J. (Bill) Greggs, **The Proctor and Gamble Company**

Bill Greggs is a Technical External Relations Manager in Procter & Gamble's Product Safety and Regulatory Affairs Division. Bill joined P&G after receiving his Bachelor of Science in Chemical Engineering from Lafayette College in Easton, Pennsylvania in 1971. He worked for 20 years in manufacturing management positions in a number of P&G's Paper product plants. Since 1990, Bill has worked on a number of legislative, regulatory and technical policy issues affecting the Company and it's products, including recycling, consumer labeling, antimicrobial product registration and chemical information sharing. Currently his focus is on chemicals management issues. He has global responsibility for P&G's involvement in HPV and Children's Health programs. For the US and ICCA HPV programs, he is involved in the development of assessments in 10 industry consortia.

Bill is a member of the American Chemistry Council Children's Health and Product Stewardship Teams. He was involved in development of the Council's proposals for assessment of chemicals in the VCCEP program and served on the VCCEP stakeholder panel. He is also active on the Alliance for Chemical Awareness Communications committee, which has developed a framework for presenting the results of screening level chemical assessments.

Stephen L. Johnson, Assistant Administrator, Office of Prevention, Pesticides and Toxic

Substances, EPA

Stephen L. Johnson is Assistant Administrator of EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS), where he has responsibility for implementing the nation's pesticide, toxic substances, and pollution prevention laws. Mr. Johnson had been Acting Assistant Administrator since January 2001. He also held top leadership positions in OPPTS since January 1999, first serving as Acting Deputy Assistant Administrator. He was named Deputy Assistant Administrator in April 2000, and then was reassigned as Principal DAA. Previously, Mr. Johnson served as Deputy Director of EPA's Office of Pesticide Programs (OPP), where he managed the nation's pesticide programs since May 1997. He also served for three years in OPP as Director of the Registration Division, where he administered the pesticide registration program, establishing or revoking pesticide tolerances and exemptions and making decisions on emergency exemptions, experimental use permits, new active ingredients, new uses, and state registrations for special local needs. Other senior level positions he has held at EPA include: Director of OPP's Field Operations Division, Deputy Director of OPP's Hazard Evaluation Division, and Executive Secretary of the Scientific Advisory Panel for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Mr. Johnson also has represented EPA in various national and international pesticide forums sponsored by the United Nations' World Health Organization and the Organization for Economic Cooperation and Development. Further, he has held staff and management positions in EPA's Office of Research and Development and Office of Toxic Substances.

A. Michael Kaplan, DuPont - Haskell Laboratory

Michael Kaplan has a B.A. in Biology from Hartwick College, an M.S. in Marine Biology from Long Island University, and a Ph.D. in Toxicology from the University of Michigan. He has worked as a toxicologist for 28 years at DuPont Haskell Laboratory for Health and Environmental Sciences doing research, testing, consulting, and management.

Michael Kaplan is currently employed by DuPont Haskell Laboratory as Director of Regulatory Affairs. He is responsible for planning and providing oversight and coordination for regulatory affairs and risk assessment activities at Haskell Laboratory and within the Corporation. He represents DuPont and its positions on regulatory affairs in numerous external forums (e.g. public hearings before regulatory agencies, inter-industry and trade associations, and direct interactions with governmental agencies –EPA; FDA; EU; OECD; etc.). In addition, he is responsible for coordinating the global technical/regulatory activities concerning the endocrine and children's health issues for DuPont. He is the chairman the ACC Children's Health Team.

Patrick Kennedy, U.S. Environmental Protection Agency

Pat Kennedy has a B.S. degree in chemistry from Portland State University and a M.S. degree in chemistry from the University of Iowa. He worked as a chemist for the U.S. Navy for 6 years

and has worked as a chemist for the Environmental Protection Agency for 17 years.

At EPA, he works on exposure assessment methods, tools, models and guidance documents. His branch is responsible for assessing and reviewing consumer, general population and environmental exposure assessments for the Office of Pollution Prevention and Toxics. He has been on the OECD Environmental Exposure Assessment Task Force since 1997 and has spent 5 years as an OPPT exposure assessment representative on EPA's Risk Assessment Forum.

George Lucier, Adjunct Senior Scientist for Environmental Defense

George Lucier is currently an adjunct toxicologist for Environmental Defense, a consultant and advisor to NIEHS, Chair of the Science Advisory Board for the Regulation of Hazardous Air Pollutants for the state of North Carolina. He is a member of the SAB for EPA on the committee for Integrated Exposure Assessment and several other boards and committees dealing with environmental health issues. Dr. Lucier retired from Director of the Environmental Toxicology Program of the NIEHS and as Associate Director of the NTP. He also retired from being editor of the Journal Environmental Health Perspectives, a post held for 28 years. He published nearly 300 scientific articles, most dealing with environmental health and risk assessment.

Jacqueline Moya, U.S. Environmental Protection Agency

Ms. Jacqueline Moya has 17 years of experience as a chemical engineer with the EPA. In 1987, Ms. Moya joined NCEA Washington (formerly the Exposure Assessment Group) where she directs research projects to develop or enhance exposure assessment methodologies and directs, conducts, and reviews exposure and risk assessments at hazardous waste sites. Ms. Moya is an expert in the area of exposure assessments and specifically on issues regarding exposure factors research, the appropriate use of exposure factors data and exposure scenarios. Ms. Moya was the project manager and contributing author in charge of the production of the U.S. EPA Exposure Factors Handbook in 1997. Since its publication, Ms. Moya has created a comprehensive program to direct research to fill data gaps found during the production of the Handbook. More recently, Ms. Moya has been in charge of producing the Child-Specific Exposure Factors Handbook as well as being a contributing author.

Nhan Nguyen, U.S. Environmental Protection Agency

Nhan Nguyen is Chief of the Chemical Engineering Branch of the Economics, Exposure and Technology Division; Office of Pollution, Prevention and Toxics. Nhan has been with the Office of Pollution Prevention and Toxics since 1989. Nhan began his career at EPA's Office of Pollution Prevention and Toxics as a staff chemical engineer. He was promoted to Senior Chemical Engineer in 1993, New Chemicals Section Chief in 1994 and later became CEB Branch Chief in 1997. Nhan's expertise includes occupational exposure assessment, release assessment, and green engineering. Nhan's EPA experience includes development of several major occupational exposure and release assessments of existing chemicals and numerous

assessments of new chemicals. Nhan also developed and contributed to technical support documents on several major rulemaking activities and other non-regulatory activities. Prior to joining the EPA, Nhan had several years of experience as a process/project engineer and shift supervisor for Monsanto and Vista Chemical. Nhan received his B.S. and M.S. degrees in Chemical Engineering from the Catholic University of America in 1983 and 1985, respectively.

Jacqueline Patterson, Toxicology Excellence for Risk Assessment (TERA)
Biography not available.

Ward Penberthy, U.S. Environmental Protection Agency

Ward Penberthy is a chemical engineer and currently serves as the Associate Director of the Chemical Control Division in EPA's Office of Pollution Prevention and Toxics. The Division provides project management, policymaking, and rule development support for the Agency's programs implementing the Toxic Substances Control Act (TSCA). Chemical testing and risk management of new and existing chemicals are among the most important responsibilities of the Division. Mr. Penberthy currently plays lead roles in the Agency's efforts related to the High Production Volume Challenge and the Voluntary Children's Chemical Evaluation Program. Mr. Penberthy has also worked extensively on exposure assessment issues while at EPA. Prior to coming to EPA, Mr. Penberthy worked for seven years in manufacturing and process design in the petrochemical industry. He has a B.S. in Chemistry from Tufts University and a Masters in Chemical Engineering from M.I.T.

Paul S. Price, The Lifeline Group

Mr. Price has a Masters degree in Civil Engineering (University of Maryland, 1979) and a Bachelors degree in Chemistry (University of Maryland, 1974). Mr. Price has more than 20 years of experience in assessing exposure to chemicals for industry, government, and trade associations. Mr. Price is a Director of The LifeLine Group, which develops software for the assessment of exposure to pesticides and other substances. He has authored over 20 articles on exposure and risk assessment and served on numerous Task Forces and External Peer Reviews for EPA, DOD, and California. Areas of interest include dose reconstruction, aggregate and cumulative risk, integration of toxicity and exposure data using simulation models, pesticide exposure, and exposures related to the consumption of fish.

Jennifer Seed, Ph.D., Existing Chemical Assessment Branch

Dr. Jennifer Seed is Branch Chief of the Existing Chemical Assessment Branch (ECAB), Risk Assessment Division of OPPT. One of the responsibilities of ECAB is to provide scientific support to VCCEP. Jennifer has been actively involved in Agency and OECD efforts to develop and harmonize test guidelines and risk assessment guidelines for developmental and

reproductive toxicity. She is a member of the Agency's Risk Assessment Forum and has been involved in Agency efforts to harmonize cancer and noncancer approaches for risk assessment, and is a member of the RfD/RfC Technical Panel. She has been involved in the FQPA 10x workgroup, as well as several ILSI workgroups. Jennifer received a Ph.D. in developmental and cellular biology from the University of Washington.

Mary Ellen Weber, Ph.D., EPA

Dr. Weber is the Director of the Economics, Exposure and Technology Division (EETD) in the Office of Pollution Prevention and Toxics, US EPA. EETD is responsible for all economic, chemical engineering, industrial chemistry, fate and transport, and consumer and occupational exposure analyses in support of chemical risk management. EETD is the National Program lead for the Inventory of TSCA chemicals manufactured or imported into the United States (Inventory Update Rule and the proposed Inventory Update Rule Amendment). Dr. Weber was co-creator of the Design for the Environment Program, Presidential Green Chemistry Program and Challenge, and the Green Engineering Program. In addition, she has promoted the development and use of models to help set priorities and aid in the design and selection of chemicals. These models include: the Risk Screening Environmental Indicators (RSEI), a.k.a. TRI Indicator, software program and database which allows the user to view all years of reported TRI data by pounds, toxicity, affected population and risk, and by media, geographic area, industry or facility. Examples of other EETD models are the Green Chemistry Expert System, Use Cluster Scoring System, and the Waste Minimization Prioritization Tool, and the Indoor Air Source Characterization Ranking Database for products of special concern to children.

Prior to her career at EPA, Dr. Weber was the founder and manager of a company that designed, programmed, and marketed occupational health and safety record keeping systems for employee health units. It was the first PC-based software of its kind and its first customer was the National Cancer Institute. Dr. Weber was also the Director of the Office of Regulatory Analysis at the Occupational and Safety Health Administration (OSHA), US Dept. of Labor, which was responsible for the engineering and economic feasibility analyses of all worker safety and health standards. Dr. Weber was the Senior Economist at the International Research and Technology Corporation forecasting the environmental impact of public interventions, e.g., energy efficiency policies, environmental taxes, subsidies, and regulations. Dr. Weber was the Country Economist for Honduras at the World Bank (IBRD) where she did both macro-economic analyses and evaluated projects in forestry, tourism, transportation, general development, and tax policies. Dr. Weber was an Assistant Professor of Economics at Smith College where she taught International Trade and Development, International Monetary Systems, and Public Finance and Taxation. Dr. Weber received her Ph.D. at the University of Utah, was a visiting scholar at Stanford, the Universidad Autonoma de Mexico, and the Universidad Catolica de Chile, and received her B.A. from the Dominican College of San Rafael, California.

Rosemary Zaleski, ExxonMobile Biomedical Sciences, Inc.

Rosemary Zaleski has a B.A. in Biochemistry from Cook College and an M.S. in Environmental Sciences from Rutgers University. She has 12 years of experience in environmental fate and effects and exposure assessment. Her experience includes multimedia and exposure modeling. Ms. Zaleski is currently employed by ExxonMobil Biomedical Sciences, Inc., in the Exposure Sciences and Human Factors Section of the Occupational and Public Health Division. She recently completed a probabilistic children's exposure assessment for the European Chemical Industry Council. She is a member of the Alliance for Chemical Awareness (ACA) technical committee, where she co-led development of an ecological exposure and risk framework and contributed to the development of human exposure frameworks. She is/has been involved in a number of American Chemistry Council exposure initiatives, including the VCCEP exposure subteam, a summary of children's exposure factors information, the review team for the USEPA Child Specific Exposure Factors Handbook, and the Exposure Action Team. Recent publications and presentations include: ECETOC Technical Report*: Exposure Factors Sourcebook for European Populations, with Focus on UK Data*, 2001 (and associated presentations at ISEA and ConSoil); Environmental Health Perspectives, Armstrong et al 2000: *A tiered approach for assessing children's exposure;* and Toxicology Letters, Armstrong et al (in press): *A tiered approach to assessing children's exposure: a review of methods and data*.